UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MICHAEL GREGORY, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. PRONAI THERAPEUTICS INC., NICK GLOVER, and SUKHI JAGPAL, Defendants.	Case No. 1:16-cv-08703-PAE CLASS ACTION **JURY TRIAL DEMANDED**

AMENDED CLASS ACTION COMPLAINT
FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

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Court-appointed Lead Plaintiffs Michael Gregory, Yeshan Jagroo and Mindy Frost ("Plaintiffs") bring this action pursuant to §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5), on behalf of all persons or entities other than Defendants (defined below) who purchased or otherwise acquired shares of ProNAi Therapeutics, Inc. ("Pronai" or the "Company")[1] securities between July 15, 2015 and June 6, 2016 (the "Class Period" and collectively the "Class").

Plaintiffs' information and beliefs, concerning matters other than themselves and their own acts, are based on the investigation of their undersigned Lead Counsel, which included, among other things, review and analysis of: (i) Pronai's public filings with the U.S. Securities and Exchange Commission ("SEC"); (ii) Pronai's other public statements, including press releases; (iii) information received from, or published by, the U.S. Food and Drug Administration ("FDA"); (iv) scientific reports concerning Pronai's clinical trials; (v) discussions with consulting experts; (vi) interviews with confidential sources who are prior employees of Pronai; and (vii) reports of securities and financial analysts, news articles, and other commentary and analysis concerning Pronai and the industry in which it operates.

Lead Counsels' investigation into the matters alleged herein is continuing, and many relevant facts are known only to, or are exclusively within the custody or control of, the Defendants. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

[1] On January 9, 2017, the Company announced that it had changed its corporate name to Sierra Oncology, Inc. and changed its NASDAQ ticker symbol to "SRRA." For the sake of clarity, the Company is referred to herein as Pronai.

SUMMARY OF THE ACTION

1. During the Class Period, Pronai (now operating as Sierra Oncology) was a clinical stage oncology company with a focus on pioneering a novel class of therapeutics based on its proprietary DNA interference ("DNAi") technology platform. PNT2258 (a DNAi drug) was the Company's only drug product candidate. During the Class Period, Pronai was conducting two Phase 2 clinical trials of PNT2258 as a third line therapy – Wolverine for the treatment of Diffuse Large B-Cell Lymphoma ("DLBCL") and Brighton for the treatment of Richter's Chronic Lymphocytic Leukemia ("RCLL"). Both trials were open-label and uncontrolled, meaning the trial data was not blinded to the parties participating in the trial and Defendants had open access to the ongoing trial results, real-time.

2. This securities fraud class action is predicated upon an extensive and pervasive fraud, orchestrated by the Defendants, who sought to force PNT2258 through its two critical Phase 2 Wolverine and Brighton trials, despite knowledge that patients were not responding to treatment with PNT2258 and in fact, were actually ***getting worse due to disease progression at rates upwards of 90%***. All the while, Defendants continued to tout the drug as positioned to "deliver extraordinary therapeutic outcomes that dramatically change patients' lives" and "change treatment paradigms across a wide range of oncology indications."

3. Throughout the Class Period, however, Defendants concealed the dismal efficacy data from the ongoing Wolverine and Brighton trials, while they secretly amended both trials' protocols in order to improve study results and report successful trials to the market. These protocol amendments began in December 2014, ***more than eighteen months*** before the interim data was publicly disclosed and ***were directly approved by Defendant Glover***, yet were inexplicably never disclosed to Pronai investors.

4. In the meantime, Pronai was able to conduct an Initial Public Offering ("IPO") of the Company's common stock at artificially inflated prices in July 2015 before three members of the Company's board of directors (the "Board"), including a majority of the Company's Audit Committee, the Chief Scientific Officer, and the Chief Medical Officer, resigned at suspicious times over the course of only five months. As these Company insiders were well aware, PNT2258 was woefully failing to establish efficacy in the Wolverine and Brighton trials and thus, would never be an approved therapy to treat DLBCL or RCLL.

5. Moreover, the Company's own internal studies and prior clinical trials of PNT2258 belied any contention regarding the purported efficacy of PNT2258 and did not provide any basis for the Defendants numerous materially false and misleading statements and omitted material facts concerning the efficacy of PNT2258, including that PNT2258:

- Had "demonstrated evidence of anti-tumor activity…suggest[ing] that PNT2258 has the potential to change treatment paradigms across a wide range of oncology indications;"
- Constituted a "unique mechanism for impacting downstream BCL2 protein levels" that "could also potentially amplify and be complementary to other therapeutic modalities;"
- Had "observed preliminary evidence of efficacy and tolerability…that we anticipate will provide the foundation of a global registration strategy for PNT2258;"
- Would be developed "for indications beyond DLBCL," to "broaden its commercial development" and "future development opportunities for PNT2258;" and
- Represented "a significant opportunity [] across many oncology indications;"

6. As set forth herein, the above statements were materially false and misleading when made because, among other reasons: (i) ongoing internal Company studies and earlier clinical trial data demonstrated PNT2258 was an ineffective treatment; (ii) efficacy data from the ongoing Wolverine and Brighton trials showed patients were not responding to treatment with PNT2258

and, rather, ***were getting worse***; (iii) as a result, Pronai was implementing numerous protocol amendments to manipulate the Wolverine and Brighton efficacy data and report successful trial results, which were ***approved by Defendant Glover***; (iv) as a result of the above, Pronai's business prospects were far worse than represented; and (v) Pronai lacked sufficient internal controls.

7. Investors would ultimately learn the truth about the efficacy of PNT2258 on June 6, 2016, when Pronai finally announced interim data from the Wolverine Phase 2 trial of PNT2258 in patients with DLBCL including that the trial had failed to establish efficacy. Pronai further announced that the Brighton trial had managed to enroll only five patients, of which, four had discontinued treatment and no responses had been observed in any patient to date. As a result, Pronai disclosed for the first time that it was suspending all clinical development of PNT2258, all further investment in the Company's DNAi platform, prematurely terminating the Brighton trial, and closing the Company's DNAi research facility in Plymouth, Michigan which had previously supported the clinical development of PNT2258.

8. On this news, the price of Pronai common stock declined from a closing share price of $6.38 per share on June 3, 2016 to close at $2.07 per share on June 6, 2016 a loss of more than 67%, on extremely heavy trading volume.

9. Defendants were aware that their statements were materially false and misleading at the time they were made because: (i) the PNT2258 clinical trials were all uncontrolled and unblinded and the Individual Defendants admittedly had access to, and did review trial results indicating that PNT2258 was failing to demonstrate efficacy; (ii) Defendants implemented numerous, undisclosed protocol amendments to the Wolverine and Brighton trials – ***approved directly by Defendant Glover*** – as they received data from the ongoing trials indicating that PNT2258 was failing to demonstrate efficacy; (iii) Defendants' own internal studies and early

clinical trials showed PNT2258 was ineffective, the results of which were presented to Defendant Glover at multiple research meetings; and (iv) PNT2258 was Pronai's "lead drug product," and "Core" business. Moreover, Defendants were motivated to commit the alleged fraud to inflate the Company's proceeds from its July 2015 IPO.

10. Plaintiffs seek to recover damages as a result of the alleged fraud.

JURISDICTION AND VENUE

11. The federal law claims asserted herein arise under §§ 10(b) and 20(a) of the Exchange Act, 15 U.S.C. § 78j(b) and § 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5, as well as under the common law.

12. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and § 27 of the Exchange Act, 15 U.S.C. §78aa. In connection with the acts, conduct and other wrongs alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the U.S. mails, interstate telephone communications and the facilities of the NASDAQ Global Select Market ("NASDAQ") (a national securities exchange located in this District). During the Class Period, Pronai's common stock traded on the NASDAQ under the symbol "DNAI."

13. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and § 27 of the Exchange Act because substantial acts in furtherance of the illegal conduct alleged herein occurred in this District. Many of the acts complained of herein, including the dissemination of materially false and misleading statements and reports prepared by or with the participation, acquiescence, encouragement, cooperation or assistance of Defendants occurred, at least in part, in this District.

THE PARTIES

I. LEAD PLAINTIFFS

14. Lead Plaintiff Michael Gregory, as previously set forth in his certification supporting his motion for appointment as Lead Plaintiff, incorporated by reference herein, purchased Pronai securities at artificially inflated prices during the Class Period and has been damaged thereby.

15. Lead Plaintiff Yeshan Jagroo, as previously set forth in his certification supporting his motion for appointment as Lead Plaintiff, incorporated by reference herein, purchased Pronai securities at artificially inflated prices during the Class Period and has been damaged thereby.

16. Lead Plaintiff Mindy Frost, as previously set forth in her certification supporting her motion for appointment as Lead Plaintiff, incorporated by reference herein, purchased Pronai securities at artificially inflated prices during the Class Period and has been damaged thereby.

II. DEFENDANTS

A. ProNAi Therapeutics, Inc.

17. Pronai is a corporation organized and existing under the laws of the State of Delaware with its corporate headquarters located in Vancouver, British Columbia, Canada. The Company is a clinical stage oncology company with a focus on pioneering a novel class of therapeutics based on its proprietary DNA interference (DNAi) technology platform. Throughout the Class Period, PNT2258 (a DNAi drug) was the Company's only drug product candidate and, thus, the successful development of PNT2258 was critical to Pronai's long-term viability. In the Company's Annual Report on Form 10-K for the year-ended December 31, 2015, filed with the SEC on March 3, 2016 (the "2015 Annual Report"), Pronai touted the importance of PNT2258's clinical success to the Company's operations and viability, stating: "[o]ur business is highly

dependent on the success of our only clinical product candidate, PNT2258 . . . Our business and future success depends on our ability to successfully develop, obtain regulatory approval for and commercialize our only clinical product candidate, PNT2258."

B. The Individual Defendants

18. Individual Defendant Nick Glover ("Glover") has been President, Chief Executive Officer ("CEO") and a member of the Pronai Board since September 2014. In the Company's SEC filings, Pronai noted the critical importance of Glover as CEO and President, by stating in relevant part: "***[w]e are dependent on our management, scientific and medical personnel, including Nick Glover, Ph.D., our President and Chief Development Officer***. . . ." (Emphasis added). Further, the Schedule 14A Proxy Statement that the Company filed with the SEC on April 27, 2016 (the "2016 Proxy Statement") in anticipation of Pronai's 2016 Annual Meeting of Stockholders encouraged stockholders to reelect Defendant Glover to the Board based on his "depth and expertise in the biopharmaceutical and venture capital industries and his extensive experience developing and managing biopharmaceutical companies." Defendant Glover has nearly twenty years of experience in drug development and commercialization, particularly with novel oncology drugs. Prior to his employment with Pronai, from June 2010 until February 2013, Glover was the President and CEO of YM BioSciences Inc., a life sciences product development company advancing a diverse portfolio of hematology and cancer-related products at various stages of clinical development. Prior to joining YM, Glover was President and CEO of Viventia Biotechnologies Inc. from January 2004 to June 2008, where he was responsible for all aspects of biotherapeutic development with a specific focus on oncology, and had taken products from discovery, through preclinical development and into global registrational clinical trials.

19. Defendant Glover participated in the management and day-to-day operations of the Company and had actual knowledge of confidential proprietary information concerning Pronai and its business, operations, growth, financial statements, and financial condition. Indeed, according to the 2016 Proxy Statement, the Company intentionally bifurcated the positions of CEO and Chairman of the Board to "***allow[] our Chief Executive Officer to focus on our day-to-day business*** while our Chairman leads our Board of Directors in its fundamental role of providing advice to and independent oversight of management." Because of his position of control and authority, his ability to exercise power and influence with respect to Pronai's course of conduct, and his access to material inside information about Pronai during the Class Period, at all relevant times, Defendant Glover was a controlling person of Pronai within the meaning of § 20(a) of the Exchange Act. As alleged herein, during the Class Period, Glover made materially false and misleading statements concerning the efficacy of the DNAi technology and PNT2258, the potential market for PNT2258 and the Company's internal controls and compliance with FDA regulations.

20. Individual Defendant Sukhi Jagpal ("Jagpal") has been Pronai's Chief Financial Officer ("CFO") since February 2015. According to the Company's SEC filings, Pronai's success was dependent on the retention of key executives including Jagpal, stating in relevant part: ***"[w]e are dependent on our management, scientific and medical personnel, including . . . Sukhi Jagpal, our Chief Financial Officer***." (Emphasis added). Moreover, as stated in the Company's June 16, 2015 Press Release announcing Defendant Jagpal's appointment as CFO, Jagpal's qualifications were necessary for the Company to "focus on rapidly advancing [its] registration-oriented clinical development program for [its] lead DNAi product candidate, PNT2258, as well as preparing for its future commercialization."

21. Individual Defendant Jagpal directly participated in the management and day-to-day operations of the Company and had actual knowledge of confidential proprietary information concerning Pronai and its business, operations, growth, financial statements, and financial condition. Moreover, because of his position of control and authority, his ability to exercise power and influence with respect to Pronai's course of conduct, and his access to material inside information about Pronai during the Class Period, at all material times, Individual Defendant Jagpal was a controlling person of Pronai within the meaning of § 20(a) of the Exchange Act. As alleged herein, during the Class Period, Jagpal made materially false and misleading statements concerning the efficacy of the DNAi technology and PNT2258, the potential market for PNT2258 and the Company's internal controls and compliance with FDA regulations.

22. Glover and Jagpal are collectively referred to herein as the "Individual Defendants." Pronai and the Individual Defendants are collectively referred to herein as the "Defendants."

STATEMENT OF FACTS

I. COMPANY BACKGROUND

A. Pronai's Financial Viability Is Dependent on the Success of Its Main Drug Product – PNT2258

23. Pronai is a clinical stage oncology company with a narrow focus on pioneering a novel class of therapeutics based on its proprietary DNA interference (DNAi) technology platform. Throughout the Class Period, the Company had only one drug product candidate, PNT2258, which was purportedly designed to target cancers that overexpress B-cell lymphoma such as Hodgkin's lymphomas and Non-Hodgkin Lymphoma ("NHL"). According to the Company's 2015 Annual Report, as of December 31, 2015, Pronai had 52 employees, most of whom were engaged in research and development.

24. As a clinical-stage Company with no approved drugs, and therefore no revenue, Pronai repeatedly acknowledged that its "business and future success depend[ed] on [its] ability to successfully develop, obtain regulatory approval for and commercialize [its] only clinical product candidate, PNT2258" and further warned that "if [it is] unable to successfully develop, obtain regulatory approval for and commercialize PNT2258, or experiences significant delays in doing so, [its] business will be materially harmed."

25. Throughout the first half of the Class Period, Pronai stated that the Company's "primary goal" and "clinical development strategy," was "to exploit the full commercial potential of PNT2258." 2015 Annual Report; *see also, e.g.*, June 16, 2015 Press Release (Company focused on "advancing [its] registration-oriented clinical development program for [its] lead DNAi product candidate, PNT2258, as well as preparing for its potential future commercialization."); June 23, 2015 Press Release (focus on "advancing our registration-oriented clinical development program for PNT2258, our lead DNAi product candidate targeting the BCL2 oncogene."); August 21, 2015 Press Release (strategy "to advance our clinical programs for PNT2258 [and] further investigate the potential breadth of opportunity of our first "DNAi-based oncology drug candidate."); October 29, 2015 Press Release (Describing Pronai as having "a comprehensive development strategy aimed at achieving efficient regulatory approval for our first DNAi-based oncology drug candidate [PNT2258]").[2]

[2] As described further in Section V, *infra*, as the Defendants learned that the Wolverine and Brighton trials were failing to meet their efficacy endpoints, the Company inexplicably changed its disclosure regarding Pronai's corporate strategy from "advancing our registration-oriented clinical development program for our lead DNAi product candidate, PNT2258" (*see* 6/16/2015 Press Release) to "building a broad and diverse pipeline of target oncology drugs" through the acquisition of new oncology therapeutics. *See* 5/26/2016 Press Release. As alleged herein, the timing of these disclosure modifications correlated with dates on which the Defendants were in possession of negative, material non-public information regarding the ongoing trials.

B. PNT2258 is a Clinical Stage DNAi-Based Therapeutic

26. Pronai's former lead product candidate and only in-Class Period drug in clinical development, PNT2258, was first developed based on the Company's own proprietary DNA interference (DNAi) technology platform. The core of the DNAi technology platform is the understanding of DNAi oligonucleotides, which are rationally designed DNA sequences that modulate the transcription of oncogenes known to be involved in cancer cell survival and proliferation. To this end, PNT2258 was designed to target BCL2, a widely overexpressed oncogene that is an important gatekeeper of the programmed cell death process known as apoptosis and has been linked to many forms of cancer. BCL2 is believed to provide certain cancer cells with the ability to resist naturally occurring apoptosis, which is a primary mechanism for the removal of aged, damaged or unnecessary cells. By promoting cancer cell survival, BCL2 overexpression contributes to tumor formation and growth, as well as the subsequent development of chemo-resistance as observed in a broad variety of tumors. It is estimated that BCL2 is expressed in more than 60 percent of all new cases across the top 10 most commonly diagnosed cancers in the United States.

27. By interfering with the transcription of BCL2, PNT2258 is designed to affect downstream BCL2 protein production, resulting in a restoration of apoptotic processes leading to the death of cancer cells. The drug is therefore distinct from traditional therapeutic approaches that target proteins through small molecules and antibodies because PNT2258 targets DNA, the upstream genetic material underlying the expression of proteins. According to the Company, the unique DNA-centric approach of PNT2258, in contrast to traditional therapies, would allow PNT2258 to more profoundly impact oncogenic targets that may be difficult to effectively drug and potentially result in enhanced efficacy, durability and safety outcomes.

28. As discussed below, during the Class Period, Defendants were developing PNT2258 as a third-line therapy for the treatment of two indications – DLBCL and RCLL. DLBCL is a cancer of B cells, a type of white blood cell responsible for producing antibodies. It is the most common type of NHL among adults, accounting for about 30 percent of newly diagnosed cases in the United States. It occurs primarily in older individuals and is an aggressive lymphoma that can arise in lymph nodes or outside of the lymphatic system in the gastrointestinal tract, testes, thyroid, skin, breast, bone, or brain.

29. RCLL is a transformation which occurs in about 5-10% of B cell chronic lymphocytic leukemia (CLL) and hairy cell leukemia into a fast-growing DLBCL, which is refractory to treatment and carries a bad prognosis. Overall, the median survival for RCLL patients is between five and eight months.

C. The Significant Potential Market for PNT2258

30. At present, there is a multi-billion-dollar unmet medical need and, thus, significant commercial potential for oncology drugs capable of impacting oncogenic targets like BCL2 after other traditional therapeutic approaches have failed. With respect to DLBCL, in particular, there are a number of other widely used anti-cancer agents that the FDA has already approved. These anti-cancer agents, unlike PNT2258, traditionally target proteins through small molecules and antibodies, resulting in decreased efficacy in patients that have not responded to multiple treatments. PNT2258, therefore, had considerable commercial potential as the ***only*** "DNAi-based product candidate in clinical development" and as a drug specifically designed to treat patients

with relapsed or refractory oncogenic conditions.[3] In addition, there are currently no specific therapies approved to treat RCLL, granting PNT2258 an effective monopoly if approved.

31. Lymphoma is the most common type of blood cancer with an estimated 81,000 new cases of lymphoma expected to be diagnosed in 2016, according to the American Cancer Society ("ACS"). NHL, which comprises more than 60 subtypes, is the most common form of lymphoma and is expected to account for approximately 73,000 new cases in the United States in 2016, according to the ACS. NHL carries a much poorer prognosis than Hodgkin's lymphoma and is expected to account for approximately 20,800 of 21,000 total annual deaths caused by lymphoma in the United States in 2016. Additionally, while incidence rates for Hodgkin's lymphoma have recently remained stable, the incidence of NHL has increased over time.

II. PRONAI'S INTERNAL STUDIES OF DNAI TECHNOLOGY AND PNT2258 DEMONSTRATED DNAI WAS AN INEFFECTIVE TREATMENT

32. According to a former research scientist at Pronai from October 2014 until June 6, 2016 who designed and executed experiments to investigate the mechanism of action of new DNAi targets such as PNT2258 as a proof of concept ("CW1"), DNAi was the piece of DNA that you deliver into the cell and that regulates gene expression. CW1 explained that DNAi is like a class of drug and PNT2258 is a DNAi drug within that class.

33. During CW1's employment at Pronai before and during the Class Period, CW1 conducted various research studies, which repeatedly showed that DNAi was ineffective and not a "real" technology. When CW1 informed Pronai management of these study results, management refused to acknowledge the failed study and kept telling CW1 to repeat the study in different ways. According to CW1, Pronai management attempted to mask the failed study results by ordering this

[3] "Relapsed" refers to a cancer that returns after a period of improvement. "Refractory" refers to a cancer that proves resistant, or does not respond to treatment.

witness to conduct the studies in different ways. Each study, according to CW1, showed that DNAi was not effective.

34. From October 2014 until February 2015, CW1 worked on the mechanism of action of PNT2258 with two other scientists during which time this witness first discovered concerns. Specifically, as CW1 explained, PNT2258 is a piece of DNA composed inside of a lipid molecule**.** When you run experiments with PNT2258, you should always have an empty lipid control, namely a lipid without the DNA because the hypothesis is that the DNA piece was causing a change and not the lipid. However, CW1 was inappropriately told by Pronai's Chief Scientific Officer, who resigned in early 2016, that the lipid control should not be run because it was not applicable to what happens in vivo.

35. CW1 confirmed this was incorrect and that, due to these erroneous instructions, CW1 and the other Pronai scientists were unsure whether any observed effects in cell death were due to lipid or DNA (in an in-vitro culture when you put lipid on cells it kills them). CW1 further confirmed that the data coming out of mouse studies in December 2015 showed no effects from PNT2258.

36. A former Pronai Research Associate from May 2015 to July 2016 responsible for preclinical research looking for mechanisms of action (*e.g.*, what the drug did at the molecular level) ("CW2") confirmed that working on the internal PNT2258 experiments was frustrating because they were looking for a signal – *e.g.*, down regulation of RNA and protein using PNT2258 – which they did not find despite, as CW1stated, changing the methodology of the studies.

37. CW1 and CW2 attended various meetings where the failed study results and problems with DNAi and/or PNT2258 were discussed. For example, CW1 and CW2 stated that they both participated in weekly internal research meetings attended by Wendi Rodrigueza, the

Chief Scientific Officer, Tom Hullinger – the Senior Director of Translational Research, Michael Woolliscroft – the Director of Program Management, and other research scientists. According to CW1, all the scientists reported the same conclusions – that DNAi and PNT2258 were ineffective. CW2 recalled Defendant Glover occasionally participating in the research meetings by video conference during which the difficulties they were having with the research for PNT2258 were discussed.

38. CW1 also participated in larger research meetings attended by Defendant Glover, other research scientists, Tom Hullinger, Wendi Rodrigueza, Gregg Smith – Vice President of Preclinical in Australia, Michael Woolliscroft, and a project management employee. CW1 recalled that these meetings occurred approximately once every quarter and, specifically, in September 2015, December 2015 and February 2016. During these meetings, Defendant Glover was briefed about the scientists' concerns relating to the study results showing DNAi and PNT2258 were ineffective. According to CW1, Defendant Glover was visibly upset about the failed study results.

39. According to CW1, with respect to the PNT2258 clinical trials (discussed further below), there were nothing but problems starting from 2015 all the way until the trials were terminated in June 2016. Specifically, CW1 stated that Pronai was "not finding any evidence to support the hypothesis at all. The hypothesis was that PNT2258 will decrease expression of BCL2 which is the gene inside cancer cells." The only thing that the scientists found was that there was a tiny bit of cell death, of which they were not sure of the source, namely whether it was the lipid. Similarly, a study investigator of PNT2258 for the Phase 2 Wolverine trial ("CW3") stated that the two patients this witness treated had no response to PNT2258.

40. Richard Messmann, former Pronai Chief Medical Officer from April 2012 until May 2016, worked in CW1's office. According to CW1, Messmann told CW1 about executive

meetings attended by Glover, Smith, Rodrigueza, and Messmann at which Messmann tried to convey his concerns about DNAi being ineffective and that Pronai needed to stop telling the public that Pronai was a DNAi company because DNAi is not real. Messmann relayed those concerns to CW1 on more than once occasion in late 2015 or early 2016.

41. Messmann told CW1 that Defendant Glover would not listen. Accordingly, Messmann resigned in April 2016.

III. THE PNT2258 CLINICAL TRIALS FOR THE TREATMENT OF DIFFUSE LARGE B-CELL LYMPHOMA AND RICHTER'S CLL

A. The ECOG Scale of Patient Performance

42. There are many factors that can predict whether a cancer patient is likely to be receptive to treatment, including their age, stage of cancer, former lines of treatment, and performance status.[4] Researchers in clinical oncology trials use the ECOG Scale of Performance Status to measure how a cancer impacts a patient's daily living abilities and to track a patient's level of functioning as a result of treatment during the trial.[5] In addition, the ECOG numbering scale is used by drug sponsors designing a clinical oncology trial to define the population of patients to be studied in the trial so that it can be uniformly reproduced among physicians who enroll patients.[6]

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[4] *Relapsed Lymphoma, Refractory Lymphoma*, LYMPHOMAINFO.NET *at* http://www.lymphomainfo.net/content/lymphoma-info/relapsed-lymphoma-refractory-lymphoma (accessed Feb. 9, 2017)

[5] ECOG-Acrin Cancer Research Group, ECOG Performance Status at http://ecog-acrin.org/resources/ecog-performance-status (visited Mar. 7, 2017).

[6] *Id*.

43. FDA Guidance cites ECOG score and baseline tumor size as the most significant risk factors for survival in oncology patients.[7] This is because patients who have a higher ECOG score and limited functional capacity tend to have more difficulty tolerating rigorous cancer treatments. These patients have less favorable outcomes than more fit patients with lower ECOG scores, regardless of the treatments given. Indeed, patients with a poor performance status – defined as a score of 2 or greater on the ECOG rating scale below – "are often excluded from clinical trials [because] they tend to have poorer responses to treatment and shorter survival than their counterparts with [ECOG] scores of 0-1."[8]

TABLE 4.1 ECOG Performance Status[a]

Grade	ECOG Performance Status
0	Fully active, able to carry on all predisease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, eg, light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

[a]*Oken MM, Creech RH, Tormey DC., et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am. J. Clin. Oncol. 1982;5:649–55.*

44. This is particularly true in patients with DLBCL. One recent study of DLBCL patients, for instance, found that third-line DLBCL patients with an ECOG score of 0-2 lived for

[7] *See* FDA Center for Drug Evaluation and Research, Advisory Committee for Pharmaceutical Science & Clinical Pharmacology March 18-19, 2008 *available at* https://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4351b1-01-FDA.pdf.

[8] Wakelee H, Rock E, Williams G, et al. Lenalidomide in combination with dexamethasone for the treatment of multiple myeloma after one prior therapy. Oncologist 2008; 13:1120-7.

a median time of 12.6 months, while those with scores higher than 2 had a median survival time of 5.3 months.[9]

45. In the same way, patients with multiple prior lines of failed therapies are less likely to respond favorably to subsequent therapy lines. For example, in a 2011 Phase 3 clinical study of Rituxan in patients with relapsed or refractory Follicular NHL, the response rate of patients to treatment decreased in parallel with their prior lines of therapies, from 82% in patients who had received one previous therapy, to 74% in patients who had received two or more prior therapies, to 62% in patients who were refractory to prior therapy.[10]

46. Accordingly, the ECOG score and prior exposure to past treatment lines within a particular patient population are primary indicators of whether oncogenic therapies will be effective.

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[9] E Van Den Neste, et al., *Outcomes of diffuse large B-cell lymphoma patients relapsing after autologous stem cell transplantation: an analysis of patients included in the CORAL study*, BONE MARROW TRANSPLANTATION *available at* http://www.nature.com/bmt/journal/v52/n2/full/bmt2016213a.html (accessed Mar. 9, 2017).

[10] *See also* Syrigos KN, Saif MW, et al.: *The Need for Third-line Treatment in Non-Small Cell Lung Cancer: An Overview of New Options*. Anticancer Res 31(2): 649-59, 2011. (Finding response rates decreased with each new line of treatment: first-line, 20.9%; second-line, 16.3%; third-line, 2.3%; fourth-line, 0%.); H. Roché, L. T. Vahdat; *Treatment of metastatic breast cancer: second line and beyond*. *Ann Oncol* 2010; 22 (5): 1000-1010. https://doi.org/10.1093/annonc/mdq429 (Finding the likelihood of response decreases by approximately one-half with each prior regimen the patient has received for metastatic breast cancer treatment. Response rates may be as high as 60%–80% with first-line treatment in patients who have not received adjuvant therapy and are ~30% and 15%, respectively, in patients who have received two or three prior regimens); Francine F, Barbara P, et al.: *Responses to romidepsin by line of therapy in patients with relapsed or refractory peripheral T-cell lymphoma*. Cancer Med. 2017, 6(1):36-44. (Citing a retrospective study of patients with Peripheral T-Cell Lymphoma demonstrated that objective response rates and rates of complete response, as well as long-term outcomes like progression-free survival worsened with each successive line of treatment).

B. Pronai's Phase 1 Dose-Escalation Study of PNT2258

47. In 2010, Pronai conducted a Phase 1 dose-escalation study of PNT2258 in 22 patients with relapsed or refractory solid tumors. The Phase 1 dose-escalation study was primarily designed to evaluate the safety and tolerability of PNT2258 in order to determine an appropriate dose and schedule for subsequent efficacy trials. The primary endpoints of the study included identification of the maximum tolerated dose of PNT2258 and characterization of its safety and toxicity profile when administered to patients with advanced solid tumors. Secondary objectives of the study included characterization of the PNT2258 pharmacokinetic profile and identification of any anti-tumor effect.

48. According to ClinicalTrials.gov (identifier number NCT01191775), inclusion criteria in the study permitted an ECOG performance status of 0-2. Of the 22 patients enrolled in the Phase 1 study, 19 or 86% had an ECOG performance scale rating of 0-1, meaning they were fully active or slightly restricted in strenuous activity but nevertheless ambulatory.[11]

49. The Phase 1 study was open-label and uncontrolled, such that the trial data was not blinded to the parties participating in the trial, including the Company's key executive team.[12] In fact, although the Company did not report the trial data until December 5, 2012, in a March 15, 2012 interview with *BioWorld Today*, Pronai's former CEO and Board member Mina Sooch revealed that "[e]arly Phase 1 data suggest[s] the trial will validate the company's preclinical

[11] Anthony W. Tolcher, *et al.*, *A phase 1 study of the BCL2-targeted deoxyribonucleic acid inhibitor (DNAi) PNT2258 in patients with advanced solid tumors*, Cancer Chemother Pharmacol. 2014; 73(2): 363–371.

[12] "Open-label" is a term used to describe the situation when both the researcher and the participant in a research study know the treatment the participant is receiving. Open-label is the opposite of double-blind when neither the researcher nor the participant knows what treatment the participant is receiving. *See Medical Definition of Open-label*, MEDICINENET.COM at http://www.medicinenet.com/script/main/art.asp?articlekey=38693 (accessed Mar. 8, 2017).

studies of PNT2258."[13] Thus, because the trial was open-label, the Company's key executive team was able to, and admittedly did, access and synthesize the Phase 1 clinical trial data as the trial was ongoing.

50. On December 5, 2012, Pronai reported its Phase 1 trial results. Notably, although overt evidence of anti-tumor effect was not a primary endpoint of the trial, of the 22 patients participating in the trial: (i) none achieved a complete response or partial response following treatment; (ii) one patient died within 30 days of trial participation; (iii) 13 patients (62%) experienced a deterioration in their condition; and (iv) 5 patients (24%) experienced a lack of any clinical benefit. In other words, 90% of the patients treated in the Phase 1 study got worse, died, or experienced no clinical benefit after treatment with PNT2258.

51. Critically moreover, Pronai only reported the pharmacokinetics of PNT2258 in the Phase 1 study and either failed to test or failed to report the pharmacodynamics of PNT2258. Pharmacokinetics is the study of the way in which drugs move through the body during absorption, distribution, metabolism and excretion and is used by drug sponsors to determine a safe and tolerable dosing regimen.[14] Pharmacodynamics, on the other hand, is the study of the way in which drugs effect the body, namely whether the drug dosed at the site of action has a resulting effect.[15] Thus, while the former implicates largely the safety profile of the drug, the latter has direct implications for a drug's ability to establish efficacy in subsequent clinical trials.

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[13] *Smarticles Extend Their Research in ProNAi's DNAi Approach*, BIOWORLD TODAY (Pub. Mar. 15, 2012) *available a*t http://www.apjohnventures.com/documents/BioWorldTodayarticle3-15-12.pdf (accessed Feb. 9, 2017).

[14] *Introduction to Pharmacokinetics and Pharmacodynamics*, AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS *available at* http://www.ashp.org/DocLibrary/Bookstore/P2418-Chapter1.aspx (accessed Mar. 15, 2016).

[15] *Id*.

52. With the omission of any pharmacodynamics data, Pronai lauded the results of the Phase 1 trial at the annual Symposium on Molecular Targets and Cancer Therapeutics as "encouraging clinical results" notwithstanding the seeming lack of efficacy in 90% of the patients who failed to respond to treatment with PNT2258. *See also* November 9, 2012 Press Release ("The encouraging clinical results from our 22 patient study, conducted at START in Texas, showed we can achieve exposure levels in humans that were many times the level needed to achieve anti-tumor effect in animals without significant liver or blood platelet toxicity…These results indicate that we can administer the drug either as a single agent or potentially in combination with other anti-cancer drugs without adding patient side effects.").

C. Pronai's Pilot Phase 2 Trial of PNT2258 in Patients with Relapsed or Refractory NHL

53. In December 2012, the Company initiated patient enrollment in its Pilot Phase 2 trial of PNT2258 for the treatment of patients with relapsed or refractory NHL. The primary objective of the Pilot Phase 2 trial was to determine PNT2258's anti-tumor activity across several hematological malignancies and to collect safety data. According to ClinicalTrials.gov (identifier number NCT01733238), of the 13 patients enrolled in the Pilot Phase 2 trial, 12 or 92.3% had an ECOG performance scale rating of 0-1, and only 1 patient had a poor ECOG performance scale rating of 2. Moreover, approximately 77% of the patient population had received two or fewer prior lines of therapy and every single DLBCL patient enrolled had an ECOG performance scale ranking of 1:

Subject No.	Diagnosis	Age (years)	ECOG PS	Disease Status (Relapsed or Refractory)*	No. Prior Lines of Therapy	Best Response on Last Prior Therapy	Time to Treatment Failure with Last Prior Therapy (months)
5	CLL	51	0	Refractory	2	SD	9.4
8	CLL/SLL	65	2	Relapsed	2	PR	21.6
2	MCL	65	1	Refractory	4	SD	5.5
6	MCL	65	0	Relapsed	4	PR	23.7
9	FL	54	1	Refractory	5	SD	5.1
3	FL	55	1	Relapsed	1	CR	21.2
7	FL	73	1	Relapsed	2	PR	35.2
4	FL	56	1	Relapsed	2	CR	48
1	FL	71	0	Relapsed	1	CR	57.9
13	DLBCL-B	61	1	Relapsed	1	CR	19.9
11	DLBCL-RT	78	1	Relapsed	2	PR	6
12	DLBCL	80	1	Relapsed	1	CR	87.6
10	DLBCL	40	1	Refractory	1	PD	2.3

Source: ProNAi Targeted Cancer Therapies ASCO Presentation (June 6, 2016) *available at* http://filecache.drivetheweb.com/mr5ircnw_pronai/124/download/ProNAi%2BASCO%2BPresentation-final.pdf.

54. The Pilot Phase 2 study, like the Phase 1 study, was open-label and uncontrolled such that the Company's key executive team was able to access and synthesize data as the trial was ongoing. In fact, although the Company did not publicly announce data from the Phase 2 trial until December 5, 2014 in a Company press release, Pronai's then-CEO, Mina Sooch, presented detailed safety and efficacy data as the trial was ongoing at the 55th Annual Meeting of the American Society for Hematology (ASH) on December 9, 2013 – an entire year earlier.[16] In addition, Pronai's key executives (including Sooch, Chief Scientific Officer Wendi Rodrigueza, and Chief Medical Officer Richard A. Messmann) summarized the data from the ongoing Pilot Phase 2 study in a medical journal sponsored by the American Society for Hematology on

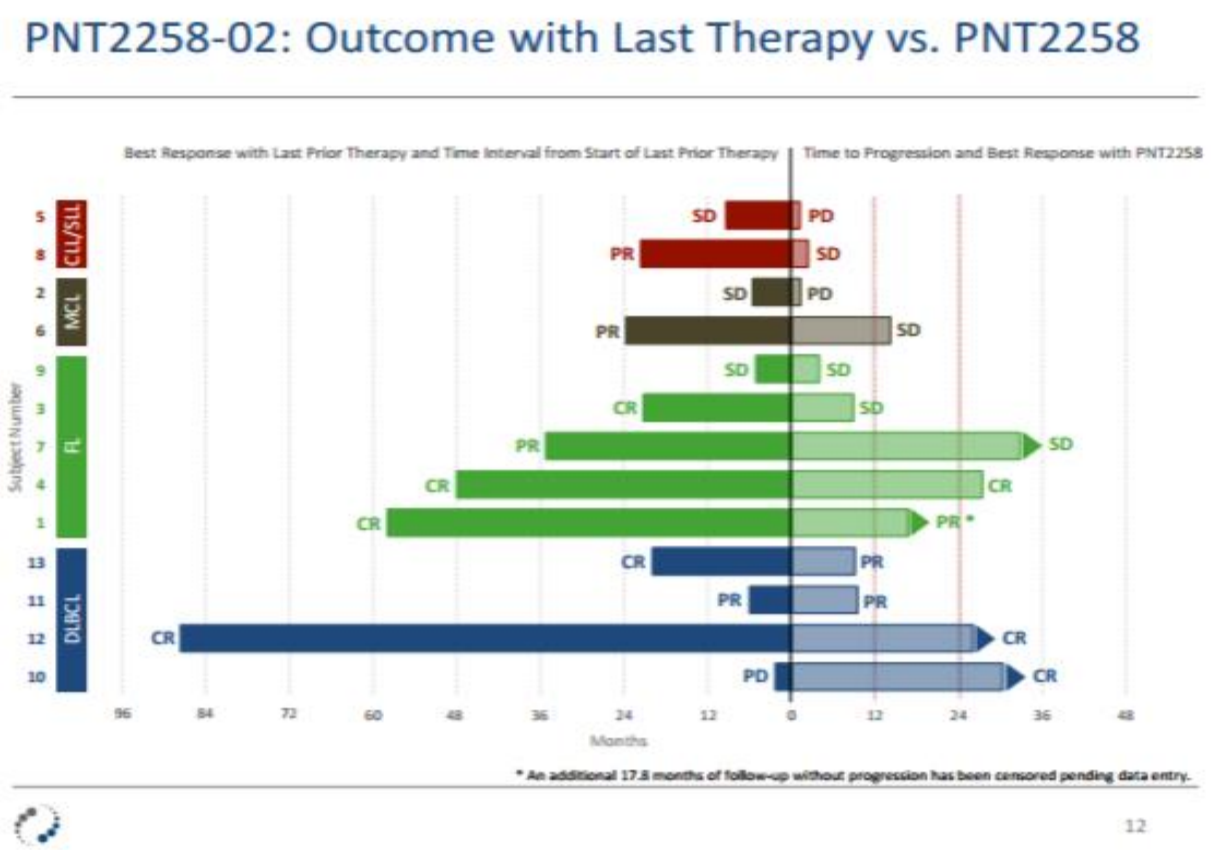
[16] *ProNAi Therapeutics Reports Anti-Tumor Activity from Ongoing Phase II Clinical Study of PNT2258, a Novel BCL2-Inhibitor, at ASH Annual Meeting*, BUSINESS WIRE (Dec. 9, 2013) at http://www.businesswire.com/news/home/20131209006427/en/ProNAi-Therapeutics-Reports-Anti-Tumor-Activity-Ongoing-Phase.

November 15, 2013, and described PNT2258 as "a promising novel approach to treating lymphoma, and cancer therapy in general."[17]

55. On December 5, 2014, the Company announced interim efficacy results for the Phase 2 trial in a Company press release, reporting that treatment with PNT2258 resulted in "significant, durable responses in patients with relapsed or refractory non-Hodgkin's Lymphoma" and is "demonstrably active in patients with diffuse large B-cell lymphoma (DLBCL)." More specifically, of the four DLBCL patients enrolled in the study, all four reportedly responded to treatment with three complete responses and one partial response. An additional notable durable complete response was reportedly achieved in *one* 79-year old male with RCLL.

56. Conspicuously, the Company only disclosed that a response had been observed in these five DLBCL and RCLL patients but never disclosed how those responses compared to the patient's prior treatment responses or how the other relapsed or refractory NHL patients in the study responded to treatment with PNT2258. Rather, as would only be revealed after the Class Period, patients in the Pilot Phase 2 study actually experienced ***disease progression at a faster rate*** compared to their prior therapies. In fact, virtually every patient in the Pilot Phase 2 study demonstrated ***a shorter interval to disease progression*** when compared to their last prior therapy:

[17] Wael A. Harb *et. al., The BCL2 Targeted Deoxyribonucleic Acid Inhibitor (DNAi) PNT2258 Is Active In Patients With Relapsed Or Refractory Non-Hodgkin's Lymphoma*, BLOOD 2013 122:88 (Pub. Nov. 15, 2013).



Source: ProNAi Targeted Cancer Therapies ASCO Presentation (June 6, 2016).

57. Further disclosed only after the Class Period, of the 13 patients treated in the Pilot Phase 2 study, 12 discontinued treatment with PNT2258 as their disease progressed and 85% of the patients treated in the study experienced one or more grade three or four adverse events. *Id*. FDA guidance defines any adverse event grade three and above as severe, meaning it results in death, is life-threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization, or results in persistent or significant disability/ incapacity. *See* 21 CFR 312.32(a).

58. Thus, consistent with the Company's internal studies, the interim data from the Pilot Phase 2 study, presented piecemeal and in a vacuum by the Defendants in December 2014, created the false impression that the Pilot Phase 2 study produced positive indicia of efficacy for

PNT2258 when in reality, patients fared far worse when treated with PNT2258 over traditional therapies.

59. Nevertheless, in complete disregard of this undisclosed data, Defendant Glover lauded the Pilot Phase 2 trial results, stating the Company would initiate further clinical testing in the ensuing months in patients with DLBCL and RCLL:

> These results demonstrate that PNT2258 is an obviously active, well-tolerated therapeutic that warrants advanced clinical development. As such, in the coming months we will be initiating robustly designed studies of PNT2258 as a single agent in patients with refractory or relapsed DLBCL and in Richter's transformed DLBCL, areas of high unmet medical need in which PNT2258 appears to be particularly effective. Given PNT2258's favorable safety profile and the prospect for a BCL2-targeted agent to augment complementary mechanistic approaches, combination clinical studies with other targeted agents are also being planned.

60. But Pronai did not wait months before initiating the next clinical study. Indeed, Pronai did not even wait for the Pilot Phase 2 trial to finish. Based only on the interim clinical response of four patients with DLBCL in the Pilot Phase 2 trial with a lower ECOG status and fewer prior treatments, the Company began enrolling patients with third-line relapsed or refractory DLBCL in the Phase 2 Wolverine trial in December 2014 – the same month the interim Pilot Phase 2 data was first disclosed. The Company would later initiate patient enrollment in the Brighton Trial for patients with RCLL – based on the clinical response of *only one patient* in the Pilot Phase 2 trial – on or about October 29, 2015.

61. These sample populations, of four and one patients respectively, were significantly below the sample populations used by all of Pronai's competitors in past Pilot Phase 2 studies of DLBCL or RCLL patients. This fact is significant because larger sample sizes generally lead to increased precision when estimating unknown parameters.[18] The sample size is also significant

[18] Several fundamental facts of mathematical statistics describe this phenomenon, including the law of large numbers and the central limit theorem, which each indicate that a larger sample

because the Defendants themselves marketed the Wolverine and Brighton trials to investors as essentially pivotal trials designed to *prove* the efficacy of PNT2258, after which a Phase 3 trial would merely be confirmatory.[19]

62. The Wolverine trial, for example, designed based only on the *interim* clinical response of *four* patients with DLBCL in the Pilot Phase 2 trial, was substantially below the historical sample sizes of various clinical studies of DLBCL patients in recent years. Exacerbating matters, the Wolverine study did not include a control group – contrary to industry practice – and used interim rather than final clinical data, further minimizing the studies' reliability and deviating from industry practice and the conventions of past studies. The chart below summarizes the sample sizes of at least 8 pilot clinical studies of DLBCL populations in recent years:

Date of Publication	Sponsor	Trial Title	Sample Size
5-10-2016	Novartis	Phase 2 study of panobinostat with or without rituximab in relapsed diffuse large B-cell lymphoma	42
12-4-2016	Abbvie	A Multicenter Open-Label, Phase 1b/2 /Study of Ibrutinib in Combination with Lenalidomide and Rituximab in Patients with Relapsed or Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL)	37
2-2017	Celgene	Phase 2 Study of Durvalumab in Combination With R-CHOP or Lenalidomide Plus R-CHOP in	120

size implies that confidence intervals are narrower and that more reliable conclusions can be reached.

[19] *See* Offering Prospectus (as defined herein) at 92 ("We plan to initiate our first combination trial in the first quarter of 2016 and a second combination trial in the third quarter of 2016. ***These two combination studies may provide opportunities to develop PNT2258 in earlier lines of therapy in DLBCL and could provide a pathway to designing a Phase 3 trial that could serve as a confirmatory trial to support full approval of PNT2258,*** if PNT2258 is approved initially based on a surrogate endpoint under accelerated approval.") (Emphasis added).

		Previously Untreated High-Risk Diffuse Large B-Cell Lymphoma	
10-2016	The Lymphoma Academic Research Organisation in collaboration with Epizyme, Inc.	Phase 2 Study of Tazemetostat in Newly Diagnosed Diffuse Large B Cell Lymphoma Patients Treated by Chemiotherapy (Epi-RCHOP)	133
12-2015	Juno Therapeutics	Phase 2 Study Evaluating the Safety and Pharmacokinetics of JCAR017 in B-cell Non-Hodgkin Lymphoma (NHL)	144
5-2013	Fred Hutchinson Cancer Research Center	Phase 1/2 Study of Laboratory Treated T Cells in Treating Patients With Relapsed or Refractory Chronic Lymphocytic Leukemia, Non-Hodgkin Lymphoma, or Acute Lymphoblastic Leukemia	169
11-2014	Karyopharm	A Phase 2b Open-label, Randomized Two-arm Study Comparing High and Low Doses of Selinexor (KPT-330) in Patients With Relapsed/Refractory Diffuse Large B-Cell Lymphoma (DLBCL)	200
July 2014	RedHill Biopharma Limited	An Early-Phase 1/2 Clinical Trial Evaluating ABC294640 in Patients With Refractory/Relapsed Diffuse Large B-cell Lymphoma (ABC-102)	33

63. Similarly, the Brighton trial was designed based on the *interim* clinical response of *only one RCLL patient* in the Pilot Phase 2 trial – again deviating from industry practice and the historical sample sizes of various clinical studies of RCLL populations in recent years. For example, Karyopharm Therapeutics Inc. recently based its pivotal trial in patients with RCLL on an open-label Phase 2 study of its drug in 50 patients.

D. The Wolverine Trial

1. Defendants Prematurely Initiate Enrollment in the Wolverine Trial Without Any Clinical Support

64. On December 28, 2014 (only three weeks after the Company announced interim data from the ongoing Pilot Phase 2 study in patients with NHL), Pronai initiated patient enrollment in the Wolverine Phase 2 study of PNT2258 for patients with relapsed or refractory DLBCL. The Wolverine trial was an open-label, non-randomized Phase 2 study without placebo controls.

65. According to the Company, the Wolverine study was "designed ***on the basis of interim results from an ongoing pilot Phase II trial of PNT2258***," meaning Pronai prematurely determined to initiate an entirely new clinical trial on the basis of only interim data from four patients who were still progressing through the Phase 2 trial protocol – again deviating from industry practice and the conventions of past studies.[20]

66. Because the Phase 2 Wolverine study, like the Company's previous trials, was open-label and uncontrolled, the Company's key executives, including Defendants, were able to, and did, access and synthesize trial data as the trial was ongoing. Indeed, although the Company did not report interim trial data from the Wolverine study until June 6, 2016, Defendant Glover provided an update on the Company's ongoing clinical development of PNT2258, including the Wolverine trial, at the 33rd Annual J.P. Morgan Healthcare Conference on January 15, 2015, more than a year before the interim data was publicly disclosed.

[20] The Company did not even announce final data from the Pilot Phase 2 trial until after the Class Period (*See* ProNAi Targeted Cancer Therapies ASCO Presentation (June 6, 2016)) and ClinicalTrials.gov shows the Pilot Phase 2 trial with a completion date of August 2016.

67. According to ClinicalTrials.gov (identifier number NCT02226965), the primary objective of the Wolverine trial was to characterize anti-tumor activity and collect safety data on approximately 60 patients with relapsed or refractory DLBCL. The original primary endpoint of the Wolverine trial was disease control rate assessed by Computerized Tomography (CT) scan, FDG-Positron Emission Tomography (PET) scan, and compared to relevant historical controls.[21] Secondary outcome measures included overall response rate, predictors of treatment outcome, and progression-free and overall survival.

68. In addition, the original inclusion criteria for the Wolverine trial permitted patients with "no limit to the number of prior therapies" and an ECOG performance status of 0-2.[22] Thus, the patient population initially enrolled in the Wolverine trial targeted patients consistent with the purpose of the trial to prove the efficacy of PNT2258 as a third-line therapy (e.g., patients with significantly worse prognoses than the patient populations enrolled in the Phase 1 and Pilot Phase 2 trials, where 86%-92.3% had a positive ECOG performance scale rating of 0-1 and had received two or fewer prior lines of therapy). Of the 37 DLBCL patients enrolled in the Wolverine trial, 27% had a clinically defined poor ECOG performance scale rating of 2 or had received four or more prior therapies.

69. Through their ongoing access to, and analysis of, the clinical trial results from the Pilot Phase 2 and Wolverine trials, Defendants learned well before Pronai announced the results of the failed Wolverine trial in June 2016 that patients were not responding to treatment with PNT2258 and/or were dropping out due to serious adverse events and/or death. Accordingly, as discussed below, Defendants repeatedly manipulated the Wolverine trial protocol based on the

[21] *View of NCT02226965 on August 26, 2014*, CLINICALTRIALS.GOV ARCHIVE *available at* https://clinicaltrials.gov/archive/NCT02226965/2014_08_26 (accessed Feb. 14, 2017).
[22] *Id.*

efficacy data they were receiving to include patients with a more favorable health profile and more achievable outcome measures. These modifications began in December 2014, years before the interim data from the Wolverine trial was publicly disclosed.

2. Pronai Repeatedly Amends the Wolverine Phase 2 Trial Protocol Prior to and During the Class Period

70. As reflected in the chart below, between December 28, 2014 and November 12, 2015, Pronai repeatedly manipulated: (i) the outcome measures for the Wolverine trial; and (ii) the inclusion criteria for participation in the trial:

Date of Modification	Description
12-22-14	• Former primary outcome measure of disease control rate modified to be secondary outcome measure; • Former secondary outcome measure of overall response rate modified to be primary outcome measure; • Timeframe to measure both extended from 4.5 to 6 months; • Adds language that disease control rate and time to response and duration of response will be based upon a blinded independent imaging review.
8-20-2015	• Timeframe to analyze primary outcome measure of time to response and duration of overall response extended from 12 months to 24 months; • Timeframe to analyze secondary primary outcome measure of Progression-free survival decreased from 24 months to 12 months; • Secondary outcome measure modified from "progression-free and overall survival" to "progression-free survival;" • Secondary outcome measure modified from "overall response rate, disease control rate, and duration of overall response" to "overall survival rate" and timeframe extended from 12 months to 24 months.
9-2-2015	• Secondary outcome measure modified from "time to response and duration of response" to "time to response;"
9-9-2015	• Timeframe to evaluate secondary outcome measure of progression-free survival extended from 12 months to 24 months;
9-10-2015	• Timeframe to evaluate secondary outcome measure of time to response decreased from 24 months to 12 months.
10-2-2015	• Following language with respect to primary outcome measure of overall response rate removed: "The overall response rate, defined by

	the proportion of patients who achieve a complete response or partial response, based upon a blinded independent imaging review." • Following language with respect to secondary outcome measure of disease control rate removed: "The disease control rate (i.e. percentage of patients with CR, PR, SD) is based upon blinded independent imaging review." • Following language with respect to secondary outcome measure of time to response removed: "Time to response is based upon blinded independent imaging review." • Following language with respect to secondary outcome measure of duration of overall response removed: "Duration of response is based upon blinded independent imaging review."
10-14-2015	• Secondary outcome measure of overall survival rate over 12 month timeframe removed – other secondary outcome measure of overall survival over 24 timeframe remained.

11-12-2015	• Secondary outcome measure of predictors of treatment outcome over 6 month timeframe removed;
	• Inclusion criteria modified as follows:
	  • Removed definitions of refractory and relapsed;
	  • Removed definition of positive scan;
	  • Prior inclusion criteria that patient must have been exposed to "at least two prior systemic regimens [with] no limit on the number of prior therapies" modified to "exposure to at least 1 or 2 but no more than 3 prior chemotherapeutic regimens;"
	  • ECOG performance status modified from "0-2" to "0-1."

71. The first major amendment to the Wolverine trial occurred on December 22, 2014 – well before the start of the Class Period – while the Defendants were in possession of material, undisclosed adverse trial data from the ongoing Pilot Phase 2 trial in patients with relapsed or refractory NHL. Although Defendants disclosed high-level response rate results from only five patients in the Pilot Phase 2 trial in December 2014, they failed to disclose how the response data compared to those patients' prior treatment responses or how the other relapsed or refractory NHL patients in the study responded to treatment with PNT2258.

72. This omission was strategic, as Defendants would only reveal after the Class Period that: (i) patients in the Pilot Phase 2 study actually experienced disease progression ***at a faster rate*** than compared to their prior therapies; (ii) of the 13 patients treated in the Pilot Phase 2 study, 12

discontinued treatment with PNT2258; and (iii) 85% of the patients treated in the study experienced one or more grade three or four adverse events. *See* ProNAi Targeted Cancer Therapies ASCO Presentation (June 6, 2016).

73. Accordingly, the Defendants' December 2014 amendment altered the primary endpoint of the Wolverine trial from disease control rate to overall response rate. Defendants knew that PNT2258 would never be able to prove disease control rate, an endpoint that is durational in nature, because they were in possession of undisclosed data from the Pilot Phase 2 study showing patients experienced disease progression at a faster rate when being treated with PNT2258 than compared to their prior therapies. Thus, the new primary endpoint of overall response rate focused the trial on the objective response of patients to PNT2258 without comparing the durational nature of that response to the patient's prior treatments. Notably, overall response rate was abandoned by the FDA as a meaningful endpoint to establish efficacy in oncology clinical trials in the 1980s.[23]

74. The December 2014 amendment also extended the timeframe for disease control assessment from 4.5 months to 6 months and increased the induction treatment phase from 6 cycles of PNT2258 to 8 cycles. These modifications reflect the Defendants' own concerns about lack of efficacy and the pharmacodynamics of PNT2258. Specifically, by extending the timeframe for assessment and increasing the number of treatment cycles, Defendants sought to boost patients' exposure to PNT2258 and produce an observable treatment response – responses that were not observed in the Pilot Phase 2 study when compared to the patients' prior treatment lines.

75. The Defendants continued to manipulate the outcome measures of the Wolverine trial throughout August and September 2015. For example, on August 20, 2015, Pronai modified

[23] *Guidance for Industry Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics*, U.S. Department of Health and Human Services, FDA (May 2007) *available at* https://www.fda.gov/downloads/Drugs/.../Guidances/ucm071590.pdf (accessed Mar. 15, 2017).

the trial's secondary outcome measure from "overall response rate, disease control rate, and duration of overall response" to "overall survival rate" – effectively abandoning any attempt to show a durational response. Of course, Defendants were well aware that PNT2258 could never establish efficacy based on durational endpoints like disease control rate or duration of overall response because they were in possession of the undisclosed data from the Pilot Phase 2 study and the ongoing Wolverine trial showing patients experienced disease progression at a faster rate when being treated with PNT2258 than compared to their prior therapies.

76. The August 2015 amendment also removed language that required an end-of-cycle 8 FDG PET scan,[24] suggesting that patients were not remaining in the study long enough to complete 8 cycles with PNT2258 either because of disease progression or because of discontinuation. Consistently, the August 2015 amendment removed as eligible patients those with high-risk aggressive histology such as DLBCL and Burkitt's-like DLBCL. This amendment, targeting the most high-risk DLBCL patients, strongly suggests the sicker patient population initially enrolled in the Wolverine trial to date had not responded to treatment with PNT2258.

77. Indeed, as the Defendants would only disclose after the Class Period with respect to the Wolverine trial: (i) 89% of the patients discontinued treatment; (ii) all 37 subjects experienced one or more adverse event; (iii) 65% of the subjects experienced one or more grade three or four adverse event; (iv) 43% of the subjects experienced a severe adverse event; and (v) 22% of the subjects had died within 30 days of their last dose of PNT2258. Moreover, of the

[24] A PET scan uses a small amount of a radioactive drug, or tracer, to show differences between healthy tissue and diseased tissue. The most commonly used tracer is called FDG (fluorodeoxyglucose). *See About PET Scans*, AMERICAN COLLEGE OF RADIOLOGY IMAGING NETWORK at https://www.acrin.org/patients/aboutimagingexamsandagents/aboutpetscans.aspx (accessed Mar. 15, 2017).

sickest patients enrolled in the study – *i.e.*, those targeted by the August 2015 amendment and the November 2015 amendment (detailed below) – none exhibited a response to PNT2258. *See* ProNAi Targeted Cancer Therapies ASCO Presentation (June 6, 2016).

78. Defendants made similar modifications to the Wolverine trial protocol in September 2015. For instance, on September 2, 2015, Pronai modified the trial's secondary outcome measure from "time to response and duration of response" to "time to response," again indicating that the Company was abandoning any attempt to show a durational response after the undisclosed Pilot Phase 2 and ongoing Wolverine trial data showed patients experienced disease progression at a faster rate when being treated with PNT2258. Duration of response is a key regulatory requirement of the FDA for the approval of any oncology drug candidate. *See supra* note 23 at 11 ("Response rates have been used in settings such as acute leukemia for regular approval.").

79. The September 2 amendments also extended the timeframe for safety outcome assessment from 6 months to 24 months, a modification strongly indicative of late, serious adverse events in the study.[25] Unbeknownst to investors at this time: (i) all 37 subjects in the study experienced one or more adverse event; (ii) 65% of the subjects experienced one or more grade three or four adverse event; and (iii) 43% of the subjects experienced a severe adverse event.

80. Moreover, throughout September 2015, Pronai repeatedly manipulated the timeframes to evaluate certain secondary outcome measures such as overall survival and time to response, indicating the Defendants were, again, engaged in data dredging to produce any

[25] *Guidance for Industry Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects*, U.S. Department of Health and Human Services, FDA (Oct. 2009) *available at https://www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf* (accessed Mar. 15, 2017).

cognizable durational response data.[26] Data dredging refers to the process of using data mining to uncover patterns in data that can be presented as statistically significant. *Id*. In other words, Defendants were attempting to manipulate the trial's efficacy data as PNT2258 continually failed to meet its predetermined endpoints, in the hope of being able to announce a statistically significant efficacy result to investors and support FDA approval.

81. Finally, on November 12, 2015, Pronai altered the inclusion criteria in the trial to skew the patient population towards healthier, more treatable patients after efficacy data from the ongoing trial showed subjects with an ECOG Performance Scale of 2 or more and/or greater than or equal to four prior lines of therapy were not responding to treatment with PNT2258. *See* ProNAi Targeted Cancer Therapies ASCO Presentation (June 6, 2016). Specifically, Defendants manipulated the inclusion criteria to limit patient enrollment to subjects with "no more than 3 prior chemotherapeutic regimens" and an ECOG performance status of "0-1," in a transparent effort to salvage the failing trial and mislead the market by reporting a positive data.

82. As Defendants would belatedly disclose after the Class Period, not only were patients in the trial not responding to treatment, but 22% of the patients enrolled between December 28, 2014 and February 29, 2016 actually died within 30 days of their last dose of PNT2258. Moreover, every single patient enrolled in the study experienced one or more adverse events with 65% of patients experiencing one or more grade three or four adverse event.[27]

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[26] Robert Kane, MD, *FDA Oncology Drug Approval, Endpoints, Effectiveness, and Approval*, Division of Drug Oncology Products, Office of Oncology Drug Products, FDA *available at* https://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ucm103366.pdf (accessed Mar. 15, 2017).

[27] Yet again, this interim data was only belatedly disclosed, after the Class Period, in a presentation by Defendant Glover at the 2016 Annual Meeting of the American Society of Clinical Oncology on June 6, 2016.

3. Defendants Directly Approved the Protocol Amendments Prior to their Submission to the FDA

83. Defendants were aware that PNT2258 was failing to establish efficacy in the Wolverine trial, and patients were not responding to treatment, because they approved and prepared the protocol amendments. Specifically, before implementing modifications to the trial protocol, Defendants would have been required to submit a protocol amendment to both the FDA and each of the Company's 27 Internal Review Boards ("IRB") supported by ***actual clinical data*** from the ongoing trial.

84. An IRB is a group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, every clinical trial site within a particular study must have its own IRB, which has the authority to approve, require modifications in (to secure approval), or disapprove research:

> For changes in a protocol, the amended study may only begin once it has been submitted to the FDA and the amended study has local IRB (Institutional Review Board) approval. Moreover, while there is no 30 day window of FDA approval, it is strongly recommended that the drug sponsor communicate with the FDA and make sure they are OK with the protocol amendment before going forward.

See 21 CFR 56.108(a)(4).

85. Pronai has acknowledged in its public filings that the Company has IRBs, for example stating in each quarterly and annual report, *inter alia*: "The trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (IRB) for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose

other conditions."[28] The Company's past studies have further represented, *inter alia*, that "[t]he institutional review board approved the protocol, and the study was registered at ClinicalTrials.gov."[29]

86. According to a former Pronai Senior Director of Biostatistics from January 2016 to September 2016 ("CW4"), Defendant Glover approved and signed all protocol amendments that constituted a major change. According to CW4, a clinical study change would be considered a major change. CW4 stated that it was in the Company's "Standard Operating Procedures" for Defendant Glover to sign and approve documents containing the amendment to be submitted to the FDA.

87. Once approved by the 27 different IRBs at each clinical trial site and Defendant Glover, Defendants would have then submitted the amendment to the FDA with supporting data from the ongoing clinical trial:

> A sponsor shall submit a protocol amendment describing any change in a Phase 1 protocol that significantly affects the safety of subjects or any change in a Phase 2 or 3 protocol that significantly affects the safety of subjects, the scope of the investigation, or the scientific quality of the study…revised protocols should build logically on previous submissions and ***should be supported by additional information, including the results of animal toxicology studies or other human studies as appropriate***.

See 21 CFR 312.30. (Emphasis added).

88. This process likely took the Defendants at least several months. For example, after the Class Period, Pronai (now operating as Sierra Oncology) initiated two new clinical trials of its

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[28] *See also* 2015 Annual Report ("[T]rial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (IRB) for approval.") (Emphasis added).

[29] Anthony W. Tolcher et al., *A phase 1 study of the BCL2-targeted deoxyribonucleic acid inhibitor (DNAi) PNT2258 in patients with advanced solid tumors*, CANCER CHEMOTHERAPY AND PHARMACOLOGY (Pub. Dec. 3, 2013) *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3909249/ (accessed Mar. 15, 2017).

recently acquired oncology asset, SRA737, and implemented protocol amendments in both trials. Not only were these amendments promptly disclosed to investors, but the Company further disclosed that it was still awaiting anticipated approval from the trials' IRBs more than two months after the amendments were first submitted.

89. Given that those trials had only three clinical trial sites, and thus significantly fewer IRBs than both the Wolverine and Brighton trials, it would have taken Defendants far longer than two months to implement the various protocol amendments in the much larger and geographically diverse Wolverine and Brighton trials. Accordingly, Defendants must have known at least several months before various protocol amendments that the Wolverine trial was failing to meet its efficacy endpoints and patients were not responding to treatment.

90. Defendants were also aware that the Wolverine trial was failing to meet its efficacy endpoints and patients were not responding to treatment because Pronai was required to monitor patient deaths and had an obligation to report each death promptly to the FDA. FDA law and regulations also required Pronai to collect and maintain information on subjects who withdraw from a clinical investigation, whether the subject decides to discontinue participation in the clinical trial (21 CFR 50.25(a)(8)) or is discontinued by the investigator because the subject no longer qualifies under the protocol (for example, due to a significant adverse event or due to failure to cooperate with study requirements).

91. Yet, inexplicably, these modifications and the efficacy data from the Wolverine trial were hidden from investors throughout the Class Period, and only belatedly disclosed in Defendant Glover's June 6, 2016 presentation at the 2016 Annual Meeting of the American Society of Clinical Oncology.

4. Defendants Violated FDA Regulations by Excluding Non-Responsive Patients from Reported Clinical Trial Results

92. Defendants also never disclosed to investors at this time that they were *excluding* the sickest patients in the study (*i.e.* those excluded by the August 2015 and November 2015 patient population amendments) from the efficacy data ultimately announced – a plain violation of FDA policy and guidance. Rather, it was only subtly disclosed in the June 6 presentation by Defendant Glover that the Company had excluded patients with an ECOG Performance Status of 2 or more and/or greater than or equal to four prior lines of therapy from the trial's efficacy data.

93. As explained by the FDA in its *Guidance for Sponsors, Clinical Investigators, and IRBs: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials* ("Guidance for Sponsors")[30]:

> FDA regulations require investigators to prepare and maintain adequate case histories recording all observations and other data pertinent to the investigation on each individual treated with the drug or exposed to the device. The agency needs all such data in order to be able to determine the safety and effectiveness of the drug or device. The fact of having been in an investigation cannot be taken back. Also, ***if a subject were able to control the use (inclusion and exclusion) of his or her data, and particularly if the clinical investigation were not blinded, the bias potential would be immense….Subjects may subsequently withdraw from such studies, but the data collected up to withdrawal may not be removed.***

(Emphasis added).

94. In its Guidance for Sponsors, the FDA explained its position by stating that:

> ***The validity of a clinical study would also be compromised by the exclusion of data collected during*** the ***study.*** There is long-standing concern with the removal of data, particularly when removal is non-random, a situation called "informative censoring…***There is particular concern with a study's reliability when subjects withdraw their data in a non-random way because they are unhappy with their experience, either because they failed to obtain a desired effect or suffered an adverse event. Loss of these subjects' data could greatly distort effectiveness***

[30] *Guidance for Sponsors*, U.S. Department of Health and Human Services, FDA, Office of the Commissioner (OC) Good Clinical Practice Program (GCPP) (October 2008) *available at* https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126489.pdf.

> ***results and could hide important safety information (for example, toxicity) of a poorly tolerated treatment. Allowing subjects to withdraw data could even provide an opportunity for unscrupulous parties to "improve" study results by selectively encouraging certain subjects to withdraw from a study.***

Id. (Emphasis added).

95. The Defendants' undisclosed modifications to the trial protocol and exclusion of the sickest patients in the study from the trial's efficacy data are therefore *exactly what the FDA has repeatedly warned against in its guidance*. Yet the Defendants' motivations for nevertheless doing so are obvious: by excluding the sickest patients in the study and altering the inclusion criteria to skew the patient population towards healthier recruits, the Defendants hoped to boost the trial's dismal efficacy performance, or as the FDA warned, "improve study results" in order to report a successful trial to the market.

96. The Company's non-disclosure of its various protocol amendments also stands in stark contrast to the industry practices of its primary competitors. While the Brighton trial (discussed below) was ongoing, for example, Karyopharm Therapeutics Inc. was the only other clinical-stage pharmaceutical company with a treatment for RCLL in clinical development. On August 10, 2015, Karyopharm announced that it had implemented a protocol amendment to its Phase 2 trial in July 2015 – only one month prior – to include patients with newly diagnosed RCLL.[31]

[31] In addition, RedHill Biopharma announced a protocol amendment to its Phase 1/2 trial in DLBCL patients in October 2016 and the trial was immediately placed on a clinical hold by the FDA; TG Therapeutics announced a protocol amendment to its Phase 3 trial in patients with NHL in October 2016 and the stock price declined approximately 17%; and Cel-Sci corporation announced a protocol amendment to its Phase 3 trial in patients with squamous cell carcinoma of the head and neck in November 2016 and the trial was immediately placed on a partial clinical hold by the FDA. Like many of the Defendants' amendments here, these protocol amendments all targeted the patient population of the study at issue.

97. The impropriety of the Defendants' in-Class Period omission is further reflected by the Company's own conduct after the Class Period. On March 2, 2017, Pronai (now operating as Sierra Oncology) announced that it had initiated two completely new clinical trials of its recently acquired oncology asset, SRA737, and had implemented protocol amendments in both trials. Specifically, Defendant Glover disclosed that the Company had submitted protocol amendments to the patient populations in both trials to evaluate the efficacy of SRA737 in subjects with advanced cancers:

> We relaunched as Sierra Oncology in January 2017, with a stated focus on developing oncology drugs targeting the DNA Damage Response (DDR) network. Recently, we successfully transferred sponsorship of the two ongoing Phase 1 clinical trials for our lead DDR drug candidate SRA737 to the company, ***which enabled us to submit protocol amendments aimed at enhancing both of these studies***. In particular, as synthetic lethality due to Chk1 inhibition has been linked to certain classes of genetic alterations, ***we plan to focus enrollment in these trials on prospectively-selected patients predicted to most likely derive benefit from SRA737 treatment based on the genetics of their tumors***. A preliminary update from the SRA737 clinical trials is anticipated to be available around the end of 2017.

(Emphasis added).

98. Not only did Defendant Glover disclose these protocol amendments, but the Company also revealed that the amendments had been submitted to the FDA and the local IRBs in January 2017 and the Company was still awaiting "anticipated approval and activation of the planned protocol amendment" in March 2017 – two months later. *See* Annual Report on Form 10-K for 2016 Fiscal Year ("We successfully transferred sponsorship of these two trials in January 2017 and subsequently submitted protocol amendments intended to enhance both of these studies."); March 2, 2017 Press Release ("Following the anticipated approval and activation of the planned protocol amendment, an algorithm based on genetic selection will be employed in order to guide patient selection.").

99. According to ClinicalTrials.gov, both Phase 1 trials of SRA737 in patients with advanced cancer had the same three clinical trial sites and thus, the same three IRBs. By contrast, the Wolverine trial had 27 trial sites and the Brighton trial had 9 trial sites. Inferably, therefore, it must have taken longer than two months to implement the various protocol amendments in the Wolverine and Brighton trials and, thus, the Defendants must have known at least several months in advance of each amendment that the trials were failing.

E. Defendants Begin Enrollment in the Brighton Trial in October 2015

1. The Brighton Trial Protocol

100. On October 29, 2015 Pronai announced that it had initiated patient enrollment in the Brighton Phase 2 study of PNT2258 for patients with RCLL. The Brighton trial was an open-label, non-randomized Phase 2 study without placebo controls. Patients in the trial were administered PNT2258 as a 4-hour IV infusion on Days 1-5 of a 21-day cycle. The efficacy evaluation for the trial was conducted through imaging evaluations conducted at baseline and after Cycles 3, 5, and 8. Accordingly, to even reach the first efficacy evaluation, patients would have to remain in the study for at least 3 Cycles, or 63 days. During the Class Period, the Defendants repeatedly stated that they expected interim data from the Brighton trial to be disclosed by the end of 2016.

101. The Brighton trial followed a similar trajectory in terms of enrolling patient with less favorable ECOG scores and many prior failed treatments population when enrollment was first initiated on or about October 29, 2015. According to ClinicalTrials.gov (identifier number NCT02378038), the original inclusion criteria for the Brighton trial permitted patients with “no

limit to the number of prior therapies" and an ECOG performance score of 0-2.[32] Of the five patients enrolled prior to the premature termination of the Brighton trial, four patients discontinued treatment – two due to death and two due to disease progression (*i.e.*, lack of efficacy). Even more troubling, the patient deaths occurred at the *outset* of the Brighton trial: one subject received only ***one dose*** of PNT2258 and died on Study Day 2 from an intracranial hemorrhage and a second subject received just ***one cycle*** of PNT2258 and died on Study Day 28.

102. Like all of the Company's previous trials, the Brighton Phase 2 trial was open-label and uncontrolled, which allowed the Individual Defendants to access and synthesize the clinical data as the trial was ongoing. For example, although the Company did not have an interim analysis for the trial scheduled until year end 2016, it prematurely announced data from the trial when revealing the Wolverine trial had failed on June 6, 2016 – nearly six months before the Company's scheduled interim look. Moreover, Defendants had an ongoing obligation to monitor and promptly report patient deaths in the trial to the FDA, which occurred almost as soon as the trial began.

103. Through their ongoing access to, and analysis of, the clinical trial results from the Pilot Phase 2 trial, the Wolverine trial, and the Brighton trial, Defendants learned well before Pronai announced the Brighton trial would be prematurely terminated in June 2016 that patients were not responding to treatment with PNT2258 and/or were dropping out due to serious adverse events and/or death. This, of course, was consistent with earlier and ongoing studies. Thus, realizing the Brighton trial, like Wolverine, was doomed to fail due to lack of efficacy, Defendants quickly and quietly amended the patient criteria in an attempt to salvage the trial, without disclosing the amendment or adverse trial results to investors.

[32] *View of NCT02378038 on March 3, 2015*, CLINICALTRIALS.GOV ARCHIVE *available at* https://clinicaltrials.gov/archive/NCT02378038/2015_03_03 (accessed Feb. 14, 2017).

2. Pronai Modifies the Brighton Phase 2 Trial Protocol During the Class Period

104. Similar to the Wolverine trial, beginning in March 2016, Pronai manipulated the inclusion/exclusion criteria for participation in the Brighton trial. Most notably, on March 10, 2016 – less than two weeks after the enrollment cut-off for interim analysis in the Wolverine trial – Pronai altered the inclusion and exclusion criteria in the Brighton trial to skew the patient population towards more treatable patients:

Date of Modification	Description
3-10-2016	• Modified inclusion criteria as follows: • ECOG performance status decreased from "0-2" to "0-1;" • Qualification that "there is no limit to the maximum number of prior therapies" is removed; EXCLUSION criteria updated to include "no more than 2 prior regimens."
6-21-2016	• Trial status updated from "recruiting" to "active, not recruiting"
6-30-2016	• Trial status updated from "active, not recruiting" to "terminated;" • Actual enrollment 5 patients.

105. As would only be revealed after the Class Period in the June 6 presentation by Defendant Glover, not only were patients in the trial not responding to treatment, but only five subjects had been enrolled in the trial to date, of which four had discontinued treatment. Of the four patients who discontinued treatment, two subjects discontinued study treatment due to death, and two other subjects discontinued treatment for progressive disease, *i.e.* because ***they got worse***, after being treated with PNT2258. Moreover, the patient deaths in the Brighton trial occurred at the ***outset*** of the trial, on Day 2 and Day 28 respectively, meaning Defendants were aware almost as soon as the trial began that patients were not responding to treatment.

106. More specifically, Defendants were aware that PNT2258 was failing to establish efficacy as the Brighton trial was ongoing because: (i) Brighton was a fully unblinded, open-label

study in which Defendants had access to the ongoing trial results; (ii) Pronai was required to monitor patient deaths and report each death promptly to the FDA; (iii) Pronai was required to collect and maintain information on subjects who withdraw from a clinical investigation; and (iv) before implementing modifications to the trial protocol, Pronai would have been required to submit a protocol amendment, ***approved by Defendant Glover***, to both the FDA and the trial's IRBs.

107. Accordingly, with full knowledge that no patient in the Brighton trial had responded to treatment with PNT2258 to date, on March 10, 2016, Defendants manipulated the inclusion criteria to limit patient enrollment to subjects with "no more than 2 prior regimens" and an ECOG performance status of "0-1" in another transparent effort to salvage the failing trial and recruit more treatable patients in order to report positive results to the market.

108. Yet again, these modifications were inexplicably never disclosed to investors in contravention of industry practices and the Company's own post-Class Period behavior, allowing the Company's common stock to remain artificially inflated throughout the Class Period.

IV. THREE MEMBERS OF THE BOARD, THE CHIEF SCIENTIFIC OFFICER, AND THE CHIEF MEDICAL OFFICER RESIGN

109. Shortly after Defendants' November 2015 protocol amendment altering the inclusion criteria for the Wolverine trial, three members of the Board (including a majority of the Company's Audit Committee), the Company's Chief Scientific Officer, and the Company's Chief Medical Officer resigned over the course of only five months.

110. On December 9, 2015, less than one month after Pronai implemented its protocol amendment to the inclusion criteria in the Wolverine trial, the Company announced that Peter Thompson, M.D., had notified Pronai of his decision to resign from the Company's Board and Audit Committee, effective December 18, 2015. Thompson had just recently been appointed to the Board in April 2014 and accordingly, his resignation came approximately 1.5 years after his

initial appointment, only five months after the Company's IPO, and less than one month after the protocol amendment to the Wolverine trial.

111. One month after Thompson's resignation, on January 25, 2016, Pronai announced that Wendi Rodrigueza had resigned, effective February 25, 2016. Prior to her resignation, Rodrigueza had been the Company's Chief Scientific Officer since February 2012 and before that, the Company's Vice President of Product Development from September 2006 to January 2012. As such, her unexplained decision to resign came after ten years of employment at Pronai, while the Company's only drug candidate was in the middle of its most important clinical trial to date, six months after the Company's IPO, approximately two months after the protocol amendment to the Wolverine trial, and in the midst of the March 2016 protocol amendment to the Brighton trial.

112. On March 4, 2016, Pronai announced that Alvin Vitangcol had resigned from the Board and Audit Committee, effective March 18, 2016. Before their resignations, Peter Thompson, M.D. and Vitangcol comprised a majority of the Company's Audit Committee. Further, prior to his resignation, Vitangcol had been a member of the Board since December 2013 and thus, his decision to resign came after three years of employment at Pronai, while the Company's only drug candidate was in the middle of its most important clinical trial to date, eight months after the Company's IPO, approximately three months after the protocol amendment to the Wolverine trial, and approximately six days before the protocol amendment to the Brighton trial was implemented.

113. Also on March 4, 2016, Pronai announced that Albert Cha had notified the Company of his decision not to stand for re-election at the Company's 2016 annual meeting of stockholders. Cha had just recently been appointed to the Board in April 2014 and, accordingly, his resignation came approximately 2 years after his initial appointment, under the same curious circumstances as Vitangcol's resignation. In fact, the Company had just stopped enrolling patients

in the Wolverine trial for purposes of the interim data analysis on February 29, 2016 – only days before the resignations of Cha and Vitangcol, and four days after the effective date of resignation for Wendi Rodrigueza.

114. Finally, both the Wolverine and Brighton trial protocols – albeit as repeatedly manipulated by the Defendants – had scheduled interim analyses of the safety and efficacy data collected by a preplanned cut-off date. An interim analysis reviews all of the safety and/or efficacy data accrued to date in order to compare treatment arms.[33] Thus, the interim analysis required the trials' researchers to formally analyze the data in a written report with respect to the trials' primary and secondary endpoints and supply that report to the trials' Data Monitoring Committees.[34] Accordingly, following the interim analyses, Defendants would no longer be able to manipulate the trial protocol in an attempt to forcibly produce efficacy results as they had been doing for years.

115. Pronai conducted its interim analysis for all data collected in the Wolverine trial on April 25, 2016 for patients enrolled as of February 29, 2016. This analysis showed indisputably that PNT2258 would fail to achieve its efficacy endpoints – regardless of how many times the Company manipulated them. *See* ProNAi Targeted Cancer Therapies ASCO Presentation (June 6, 2016). While this data would not be revealed to Pronai investors for several more months, only

[33] *See International Conference on Harmonization (ICH) guidance*, E9 Statistical Principles for Clinical Trials, §4.5 (1998) ("ICH E9 Guidance") (Interim analysis "is any analysis intended to compare treatment arms with respect to efficacy or safety at any time prior to formal completion of the trial[.]"). Thus, "[i]nterim analysis requires unblinded…access to treatment group assignment (actual treatment assignment or identification of group assignment) and comparative treatment group summary information." *Id*.

[34] A Data Monitoring Committee ("DMC") "may be established by the sponsor to" review the accumulating safety surveillance data and "assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial." TGA GCP Guide §1.25. "In some cases, a specific independent committee with substantial external representation could be created to perform this function. In others, the sponsor may choose to create a safety team within the sponsor's organization." FDA Safety Reporting Guide at 13.

the following day, on April 26, 2016, Pronai's Chief Medical Officer Richard Messmann resigned, effective May 26, 2016.

116. Prior to his resignation, Messmann had been the Company's Chief Medical Officer since April 2012. As such, his unexplained decision to resign came after four years of employment at Pronai, while the Company's only drug candidate was in the middle of its most important clinical trial to date, less than one year after the Company's IPO, and *one day* after the Company's interim analysis of the Wolverine trial data.

V. KNOWING THE WOLVERINE AND BRIGHTON TRIALS ARE LIKELY TO FAIL, PRONAI MODIFIES ITS DISCLOSURES REGARDING CORPORATE STRATEGY

117. In the midst of the legion of Pronai Board members and senior executives who resigned or were fired following the protocol amendments to both the Wolverine and Brighton trials, the Company subtly and inexplicably altered its disclosures regarding its corporate strategy.

118. As briefly mentioned *supra* I.A., throughout the first half of the Class Period, the Company's self-proclaimed "primary goal" and "clinical development strategy," was "to exploit the full commercial potential of PNT2258 by developing the product candidate in earlier lines of therapy in DLBCL." And indeed, Pronai's public statements at the beginning of the Class Period indicate that the clinical development of PNT2258 was the Company's *only* focus and *only* corporate strategy.

119. Yet over the course of the Class Period, as Pronai continued to receive efficacy data from the Wolverine and Brighton trials, this language was modified and later entirely abandoned, while the Company's purported corporate strategy focused on PNT2258 was replaced with a corporate strategy focused on "building a broad and diverse pipeline of target oncology drugs"

through the acquisition of new oncology therapeutics. *See* May 26, 2016 Press Release. This disclosure evolution is reflected in the chart below:

Date	Document	Disclosure
8-21-2015	Press Release announcing Q2 2015 Results.	"During the second quarter we continued to advance our clinical programs for PNT2258…***We plan to initiate three additional Phase 2 trials in 2016 with PNT2258 to further investigate the potential breadth of opportunity of our first DNAi-based oncology drug candidate***."
10-29-2015	Press Release announcing enrollment of Brighton trial	"Brighton is the second Phase 2 trial we have recently initiated with PNT2258 as part of a ***comprehensive development strategy aimed at achieving efficient regulatory approval for our first DNAi-based oncology drug candidate***. ***We also plan to initiate additional Phase 2 trials in 2016 with PNT2258***."
11-5-2015	Press Release announcing Q3 2015 Results	"With [Wolverine and Brighton] trials underway, ***we are now preparing planned Phase 2 trials of PNT2258 in combinations with other therapeutics in patients with earlier lines of DLBCL and anticipate initiating the first of these trials in the first half of 2016***."
12-3-2015	Press release announcing new of Senior Management Team	"Dr. [Gregg] Smith [appointed as Vice President, Preclinical] will play a key role in ProNAi's portfolio expansion activities…by being ***actively involved in the search, evaluation and development planning of any potentially acquirable oncology drug assets***."
3-3-2016	Press release announcing 2015 year-end results	"***We are also designing a number of additional Phase 2 trials that could support the registration and commercialization strategies for PNT2258. Two planned trials, Cypress and Granite, will evaluate PNT2258 in combination with standard-of-care treatment regiments*** for the treatment of second-line DLBCL in the "transplant eligible" and "transplant" ineligible" patient populations. ***We are also designing trials evaluating PNT2258's potential in DLBCL*** in combination with a targeted anti-cancer drug, and in other hematological malignancies as well."
5-10-2016	Press release announcing Q1 2016 Results	"***[W]e continue to evaluate novel drug candidates for potential licensing or acquisition, with the vision of establishing a broad and diversified pipeline under our development. Supporting this vision***, in the first quarter we further strengthened Pronai's core infrastructure by adding two industry veterans to our Board of Directors."

5-26-2016	Press release announcing acquisition of new cancer drug	Company "today announced it has obtained an exclusive license from Carna Biosciences, Inc., Kobe, Japan, for worldwide rights to develop and commercialize As-141, a small molecule kinase inhibitor targeting CDC7…***This agreement, and our focused efforts to identify additional high-quality assets to acquire, reflect our strategy of building a broad and diverse pipeline of target oncology drugs that will change people's lives***."
6-1-2016	Press release announcing new Senior Vice President of Research	"[Dr. Chris Hassig] will play an integral role in the identification, selection and validation of targets and novel drug candidates."

(Emphasis added).

120. As the above chart shows, the Company's corporate "strategy" inexplicably changed from, on the one hand, "advancing our registration-oriented clinical development program for our lead DNAi product candidate, PNT2258, as well as preparing for its potential future commercialization" (*e.g.*, June 16, 2015 Press Release)[35] to, on the other hand, "building a broad and diverse pipeline of target oncology drugs" through the acquisition of new oncology therapeutics. *See* May 26, 2016 Press Release.[36] Analysts noticed the trend as well, with Jefferies

[35] *See also* 6/18/2015 Press Release ("[A]dvancing our registration-oriented clinical development program for PNT2258, our lead DNAi product candidate targeting the BCL2 oncogene."); 6/23/2015 (Exploring "the scope of opportunity for our lead DNAi-based cancer drug, PNT2258, and for the broader potential of the DNAi technology platform underlying our novel approach to treating cancer."); 8/21/2015 Press Release ("[T]o advance our clinical programs for PNT 2258 [and] further investigate the potential breadth of opportunity of our first "DNAi-based oncology drug candidate.").

[36] 12/3/2015 Press Release ("[B]eing actively involved in the search, evaluation and development planning of any potentially acquirable oncology drug assets."); 5-10-2016 Press Release ("[C]ontinue to evaluate novel drug candidates for potential licensing or acquisition, with the vision of establishing a broad and diversified pipeline under our development."); 5-26-2016 Press Release ("[F]ocused efforts to identify additional high-quality assets to acquire, reflect our strategy of building a broad and diverse pipeline of target oncology drugs that will change people's lives."); 6-1-2016 Press Release ("[P]lay an integral role in the identification, selection and validation of targets and novel drug candidates.")

expressing concerns in a May 11, 2016 research note that the Company's "shifting strategy" could reflect "limitations emerging in the ongoing data."

121. Indeed, the timing of the disclosure modifications often correlated with dates on which the Defendants were in possession of negative, material non-public information regarding the ongoing Wolverine and Brighton trials. For example, the Company first mentioned the potential acquisition of a new "oncology drug asset[]" on December 3, 2016, less than one month after it implemented a protocol amendment to the Wolverine trial to skew the patient population towards healthier, more treatable patients. Only six days after this disclosure modification, on December 9, 2016, Pronai announced that Peter A. Thompson, M.D. would resign effective December 18, 2016.

122. Additionally, the Company's first mention of the Cypress and Granite Phase 2 trials for PNT2258, on March 3, 2016, was swiftly abandoned when Pronai implemented a protocol amendment to the Brighton trial only seven days later, on March 10, 2016. In the midst of this modification, on March 4, 2016, both Alvin Vitangcol and Albert Cha resigned from the Board. Thereafter, Pronai repeatedly admitted to hiring new Company executives for the express purpose of acquiring other oncology drug candidates and entirely abandoned discussing additional Phase 2 trials for PNT2258.

VI. DAYS BEFORE TRIAL FAILURE IS REVEALED, PRONAI USES PROCEEDS FROM INITIAL PUBLIC OFFERING TO FUND ACQUISITION OF ALTERNATIVE DRUG CANDIDATE

123. Even after the Defendants: (i) learned of undisclosed data from the Pilot Phase 2 study showing patients experienced disease progression at a faster rate when being treated with PNT2258 than compared to their prior therapies; (ii) repeatedly amended the trial protocol for both the Wolverine and Brighton trials; and (iii) conducted an interim analysis inexplicitly showing

PNT2258 would never establish efficacy, they continued to reassure investors that the Company's sole focus was "advancing [its] registration-oriented clinical development program for [its] lead DNAi product candidate, PNT2258, as well as preparing for its potential future commercialization." *See e.g.*, June 16, 2016 Press Release.

124. In reality, however, Defendants were aware that both the Wolverine and Brighton trials were woefully failing to meet their efficacy endpoints and three days before announcing the failure of both trials, used the proceeds raised in the Company's July 2015 IPO to fund the acquisition of an alternative drug candidate. To initially peddle its IPO shares to unsuspecting investors, Pronai filed its Offering Prospectus on Form 424B4 with the SEC on July 16, 2015 (the "Offering Prospectus").

125. The Offering Prospectus represented to Pronai investors that proceeds from the public offering would be primarily used to "fund [its] ongoing Wolverine Phase 2 trial, [its] planned Brighton Phase 2 trial…and manufacturing activities related to these trials; to fund other planned future Phase 2 trials related to PNT2258 and manufacturing activities related to these trials; [and] to support non-clinical activities and preclinical activities related to PNT2258, including activities related to its mechanism of action." Accordingly, of the anticipated $124.4 million raised in the IPO, Pronai purportedly intended to spend $88 million on the clinical development of PNT2258 and reserved only $7 million "to further develop our DNAi technology platform and broaden our pipeline of DNAi-based product candidates."

126. On July 21, 2015, Pronai announced the close of its IPO of 9.315 million shares of common stock at a public offering price of $17.00 per share for gross proceeds of $158.4 million, before deducting underwriting discounts and commissions and estimated offering expenses. Despite its representations to investors, however, Pronai would never use these proceeds to fund

other clinical trials of PNT2258, or manufacture and commercialize PNT2258, or even expand the Company's pipeline of DNAi-based candidates.

127. Rather as discussed *supra* V, beginning in at least December 2015, the Company shifted its focus and use of proceeds from developing PNT2258 in various ongoing and planned clinical trials to hiring executives for the express purpose of identifying and acquiring new drug candidates. To this end, Pronai: (i) hired Dr. Gregg Smith on December 3, 2015 as the Company Vice President of Preclinical to be "actively involved in the search, evaluation and development planning of any potentially acquirable oncology drug assets;" (ii) added Jeffrey H. Cooper and Tran Nguyen to the Board during the first quarter 2016 "to evaluate novel drug candidates for potential licensing or acquisition, with the vision of establishing a broad and diversified pipeline under our development;" and (iii) hired Dr. Chris Hassig on June 1, 2016 to "play an integral role in the identification, selection and validation of targets and novel drug candidates."

128. These hiring efforts culminated in the Company's public announcement on May 26, 2016 – three business days before announcing the Wolverine and Brighton trial failures – that Pronai had obtained an exclusive license from Carna Biosciences, Inc. for worldwide rights to develop and commercialize AS-141, a small molecule kinase inhibitor targeting CDC7. Under the terms of the agreement, Pronai was required to pay Carna Biosciences an initial upfront payment of $0.9 million and aggregate additional potential payments upon achievement of certain developmental, regulatory and commercial milestones of up to $270 million. As the Company's only revenue source in recent years, and as the Defendants later admitted in its Form 10-Q for the

second quarter of 2016, filed on August 12, 2015 ("2016 Second Quarter Report"), this acquisition was funded by proceeds from the IPO.[37]

DEFENDANTS' MATERIALLY FALSE AND MISLEADING CLASS PERIOD STATEMENTS AND OMISSIONS

129. As alleged herein, prior to and throughout the Class Period, Defendants were in possession of clinical trial data showing that PNT2258 was failing to meet its efficacy endpoints and, thus, both the Wolverine and Brighton trials were "not trending to an outcome that supports the likelihood of registration [with the FDA]" and not "robust enough to justify continued development of the drug." Indeed, as alleged herein, Defendants repeatedly manipulated both the Wolverine and Brighton trial protocols based on the efficacy data Pronai was receiving prior to and throughout the Class Period, and well before the interim Wolverine trial data was publicly disclosed.

130. Yet inexplicably, throughout the Class Period, the Individual Defendants concealed the truth regarding PNT2258's lack of efficacy and continued to falsely assure investors that PNT2258 was positioned to "deliver extraordinary therapeutic outcomes that dramatically change patients' lives" and "change treatment paradigms across a wide range of oncology indications." These material misstatements and omissions, among others, created the false impression that the PNT2258 trials were demonstrating positive results and that PNT2258 was on track to receive

[37] *See* 2016 Second Quarter Report at 53 ("On July 15, 2015, our Registration Statement on Form S-1 (File No. 333-204921) relating to the IPO of our common stock was declared effective by the SEC. In June 2016, we halted investment in PNT2258, our former lead product candidate, based on our review of the interim results from a Phase 2 trial of PNT2258. Accordingly, we now intend to use the remaining net proceeds from our IPO to advance the development of PNT141, acquire or in-license additional product candidates and technologies and for other general corporate purposes.")

FDA approval as a third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL and caused the Company's stock price to be artificially inflated throughout the Class Period.

131. As discussed below, the above statements were false and misleading because Defendants did not disclose that: (i) the Company's ongoing experiments and studies indicated DNAi and PNT2258 were ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; (iii) the Wolverine and Brighton trial data Defendants were receiving on an ongoing basis showed PNT2258 lacked efficacy; (iv) as a result of the lack of efficacy, Defendants repeatedly amended the Wolverine and Brighton trial protocols throughout the Class Period; (v) PNT2258 could never be approved as a third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL; (vi) Defendants intended to exclude the sickest patients in the Wolverine trial (*i.e.*, those excluded after the protocol amendment) from the efficacy analysis and trial results, even though those patients participated in the trial; and, thus (vii) Pronai was in violation of FDA regulations.

I. MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS IN PRONAI'S OFFERING PROSPECTUS

132. On July 16, 2015, the beginning of the Class Period, the Company filed its Offering Prospectus with the SEC, which contained several categories of materially false and misleading statements concerning: (i) the efficacy of PNT2258 and the DNAI platform; (ii) the potential market for PNT2258 and the DNAI platform; and (iii) the Company's compliance with FDA regulations.

A. False and Misleading Statements Concerning the Efficacy of PNT2258

133. In the Offering Prospectus, Defendants falsely represented that PNT2258 had produced "evidence of efficacy and tolerability [and] the potential to change treatment paradigms across a wide range of oncology indications:"

> Our lead DNAi product candidate, PNT2258, targets BCL2, a widely overexpressed oncogene that is an important gatekeeper of the programmed cell death process known as apoptosis and has been linked to many forms of cancer. In a recent single-agent Phase 2 trial of 13 patients with relapsed or refractory non-Hodgkin's lymphoma (NHL), ***PNT2258 demonstrated evidence of anti-tumor activity, with 11 patients achieving a complete response (CR), partial response (PR) or stable disease (SD)***. Furthermore, all four of the diffuse large B-cell lymphoma (DLBCL) patients treated in this trial ***experienced a clinical response, including three CRs and one PR***, with reported durations on study in the range of nine to more than 20 months. Although not statistically powered for a formal efficacy analysis, ***we believe the preliminary evidence of efficacy observed in this trial, coupled with safety and tolerability data collected to date, suggest that PNT2258 has the potential to change treatment paradigms across a wide range of oncology indications***.

(Emphasis added).

134. Moreover, the Individual Defendants falsely touted in the Offering Prospectus the DNAi platform's purportedly "***unique mechanism for impacting downstream BCL2 protein levels"*** that ***"could also potentially amplify and be complementary to other therapeutic modalities"*** and the implications that platform would have for PNT2258's "enhanced efficacy." (Emphasis added).

135. The Offering Prospectus further misrepresented the following regarding the Company's DNAi platform and the implications that platform would have for PNT2258:

> ***We believe that DNAi technology may be applicable to additional high value genetic targets beyond BCL2 that are also challenging to drug by conventional means***. ***We plan to leverage our DNAi technology platform to generate a pipeline of product candidates that modulate the transcription of oncogenes known to be involved in cancer***, and potentially genes implicated in other diseases.

(Emphasis added).

136. The above statements were materially false and misleading when made because: (i) ongoing studies and internal Company experiments demonstrated DNAi and PNT2258 were ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; (iii) efficacy data from the ongoing Wolverine trial showed enrolled patients were not responding to treatment with PNT2258; (iv) as a result, Pronai was implementing numerous protocol amendments to manipulate the Wolverine efficacy data and report successful trial results; (v) PNT2258 would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL, and the Company would never submit an NDA to the FDA for those indications; (vi) the Company had materially overstated the efficacy of PNT2258 and its business prospects; (vii) as a result of the above, Pronai's business prospects were far worse than represented; and (viii) Pronai lacked sufficient internal controls.

137. Finally, the Individual Defendants purportedly warned investors of the risks it faced if PNT2258 was unsuccessful stating for example that "our business is highly dependent on the success of our only clinical product candidate, PNT2258. If we are unable to successfully develop, obtain regulatory approval for and commercialize PNT2258, or experience significant delays in doing so, our business will be materially harmed:"

> Our business and future success depends on our ability to successfully develop, obtain regulatory approval for and commercialize our only clinical product candidate, PNT2258, which is at an early stage of development.
>
> * * *
>
> If clinical trials of PNT2258 or future product candidates that we may develop fail to demonstrate safety and efficacy or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of PNT2258 or future product candidates.

138. These purported warnings were materially false and misleading because, at the time that Defendants made these purported warnings, Pronai was in possession of clinical trial data showing that PNT2258 was failing to meet its efficacy endpoints and as a result, would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL. Accordingly, the very risks Defendants were warning investors about had already materialized.

B. False and Misleading Statements Concerning the Potential Market for PNT2258

139. In the Offering Prospectus, Defendants falsely represented that Pronai would become "a leader in developing and commercializing a broad and diverse portfolio of cancer therapies and deliver therapeutic outcomes that dramatically changed patients' lives." In support of this strategy, Defendants specifically noted that "[h]aving ***observed preliminary evidence of efficacy and tolerability,*** we plan to pursue a broad registration-oriented clinical development program, initially in hematologic malignancies, ***that we anticipate will provide the foundation of a global registration strategy for PNT2258***." (Emphasis added).

140. In more detail, Defendants falsely represented with respect to the Company's development strategy for PNT2258:

Our Strategy

Key elements of our business strategy are to:

- ***Expedite the Clinical Development and Regulatory Approval of PNT2258***. ***We plan to advance our lead product candidate, PNT2258, in DLBCL and Richter's CLL and may pursue accelerated registration paths and other regulatory designations if data are compelling***. In December 2014, we initiated Wolverine, a Phase 2 trial for the treatment of third-line relapsed or refractory DLBCL, and by mid-2015, we plan to initiate Brighton, a Phase 2 trial for the treatment of Richter's CL.

- ***Pursue a Multi-Faceted Development Strategy for PNT2258 Across Many Oncology Indications***. In addition to Wolverine and Brighton, ***we intend to***

expand the commercial market opportunity for PNT2258 by developing it for the treatment of a wide variety of BCL2-driven tumors, including other hematologic malignancies, such as leukemias and myelomas, as monotherapy and in combination with other therapeutic agents or treatment regimens. BCL2 overexpression has also been implicated as a driver of a wide variety of solid tumors, including breast, prostate and lung, which could provide additional ***future development opportunities for PNT225***8.

- ***Maximize the Global Commercial Value of PNT2258.*** We have retained all commercial rights to PNT2258 and future DNAi product candidates. ***As we further develop PNT2258, we plan to build a commercial infrastructure to directly market in North America and possibly other major geographies that are core to our commercial strategy. We plan to enter into collaborations for the development, marketing and commercialization of PNT2258 in additional geographies at an appropriate time. We also plan to invest in scaling our manufacturing capacity to support our global commercial strategy***.

- ***Maintain our Competitive Advantage by Continuing to Invest in our Proprietary DNAi Technology Platform.*** We plan to continue to conduct research in the field of DNAi to further our understanding of the role this technology plays in modulating gene transcription. We also plan to continue fostering relationships with leading scientific advisers and physicians to support these efforts.

- ***Broaden our Pipeline of Novel Product Candidates by Leveraging our Proprietary DNAi Technology Platform.*** We believe DNAi technology may be ***applicable to additional high value genetic targets beyond BCL2 that are also challenging to effectively drug by conventional means***.

(Emphasis added).

141. Defendants also falsely represented that "our technology, knowledge, experience, and scientific resources provide us with competitive advantages" and further touted the commercial viability of PNT2258 post-FDA approval:

Since we estimate that BCL2 is expressed in more than 60% of all new cases across the top 10 most commonly diagnosed cancers in the United States, we are also interested in developing PNT2258 for indications beyond DLBCL.

> Specifically, BCL2 is highly overexpressed in various other hemotologic malignancies. We plan to initiate a trial in the second quarter of 2016 to test the potential efficacy of PNT2258 as a single agent in the treatment of late stage AML, ALL and MM. If initial results are promising, this trial may provide a basis for subsequent clinical development, facilitating PNT2258's entry into additional cancer indications to ***further broaden its commercial potential***. BCL2 overexpression has also been implicated as a driver of a wide variety of solid tumors, including breast, prostate and lung, which could provide ***additional future development opportunities for PNT2258***.

(Emphasis added).

142. In addition, Defendants represented that there was purportedly "a significant opportunity to develop PNT2258 across many oncology indications:"

> Since we estimate that BCL2 is expressed in more than 60% of all new cases across the top 10 most commonly diagnosed cancers in the United States, we believe ***there is a significant opportunity to develop PNT2258 across many oncology indications***.

(Emphasis added).

143. According to Defendants, the Company was pursuing "***a multi-faceted clinical development strategy that is designed to achieve regulatory approval and maximize the commercial opportunity of PNT2258***." (Emphasis added). Indeed, Defendants even warned that "[o]ur competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market," thus implying that FDA approval of PNT2258 was a sure thing.

144. The above statements were materially false and misleading when made because: (i) ongoing studies and internal Company experiments demonstrated DNAi and PNT2258 were ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; (iii) efficacy data from the ongoing Wolverine trial showed patients were not responding to treatment with

PNT2258 and, thus, the potential market for PNT2258 was significantly less than represented or nonexistent; (iv) PNT2258 would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL, and the Company would soon abandon its corporate development strategy; (v) the Company had materially overstated the efficacy of PNT2258 and its business prospects; and (vi) as a result of the above, Pronai's business prospects were far worse than represented.

C. Materially False and Misleading Statements Concerning Compliance with FDA Regulations

145. The Offering Prospectus contained numerous false representations and purported warnings to investors regarding the Company's compliance with FDA regulations and the risks associated thereto. For example, the Individual Defendants purportedly warned investors of the risks Pronai faced in connection with FDA oversight of the Wolverine and Brighton trials, stating that "[w]e may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed:"

> Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the study sites where the clinical trials are conducted…***Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including***:
>
> - ***deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols***;
> - deficiencies in the clinical trial operations or trial sites;
> - the product candidate may have unforeseen adverse side effects;
> - ***deficiencies in the trial design necessary to demonstrate efficacy***;
> - ***fatalities or other AEs arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;***
> - ***the product candidate may not appear to be more effective than current therapies***; or

- the quality or stability of the product candidate may fall below acceptable standards.

Although we have never been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial, ***if we elect or are forced to suspend or terminate a clinical trial of any other of our product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners***.

(Emphasis added).

146. The above statements were materially false and misleading when made because: (i) Pronai was implementing numerous protocol amendments to manipulate the Wolverine efficacy data and report successful trial results; (ii) Pronai planned to exclude the sickest patients in the Wolverine study from the efficacy data ultimately announced in June 2016; (iii) as a result, Pronai was not in compliance with FDA regulations and PNT2258 would never be an approved therapy for patients with relapsed or refractory DLBCL and/or RCLL.

147. Throughout the Class Period, the above misstatements served to facilitate and inflate the Company's proceeds raised in the IPO. Pronai announced the close of its IPO of 9.315 million shares of common stock at a public offering price of $17.00 per share for gross proceeds of $158.4 million on July 21, 2015.

II. MATERIALLY FALSE AND MISLEADING STATEMENTS IN PRONAI'S 2015 SECOND QUARTER REPORT

148. On August 21, 2015, the Company filed its quarterly report on Form 10-Q with the SEC for the second quarter ended June 30, 2015 ("2015 Second Quarter Report"), which was signed and certified by Individual Defendant Glover. The 2015 Second Quarter Report contained several categories of materially false and misleading statements relating to: (i) the efficacy of

PNT2258; (ii) the potential market for PNT2258 and the DNAi platform; and (iii) Pronai's compliance with FDA regulations.

A. False and Misleading Statements Concerning the Efficacy of PNT2258

149. In the 2015 Second Quarter Report, Defendants falsely represented that PNT2258 had produced "evidence of efficacy and tolerability:"

> Our lead DNAi product candidate, PNT2258, targets BCL2, a widely overexpressed oncogene that is an important gatekeeper of the programmed cell death process known as apoptosis and has been linked to many forms of cancer. In a recent single-agent Phase 2 trial of 13 patients with relapsed or refractory non-Hodgkin's lymphoma (NHL), ***PNT2258 demonstrated evidence of anti-tumor activity, with 11 patients achieving a complete response (CR), partial response (PR) or stable disease (SD). Furthermore, all four of the diffuse large B-cell lymphoma (DLBCL) patients treated in this trial experienced a clinical response, including three CRs and one PR***, with reported durations on study in the range of nine to more than 20 months. Although not statistically powered for a formal efficacy analysis, ***we believe the preliminary evidence of efficacy observed in this trial, coupled with safety and tolerability data collected to date, suggest that PNT2258 has the potential to change treatment paradigms across a wide range of oncology indications. Accordingly, we plan to pursue a broad registration-oriented clinical development program, initially in hematologic malignancies, that we anticipate will provide the foundation of a global registration strategy for PNT2258***.

(Emphasis added).

150. The above statements were materially false and misleading when made because: (i) ongoing studies and internal Company experiments demonstrated DNAi and PNT2258 were ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; (iii) efficacy data from the ongoing Wolverine trial showed enrolled patients were not responding to treatment with PNT2258; (iv) as a result, Pronai was implementing numerous protocol amendments to manipulate the Wolverine efficacy data and report successful trial results; (v) PNT2258 would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL, and the Company would never submit an NDA to the FDA for those indications; (vi) the

Company had materially overstated the efficacy of PNT2258 and its business prospects; (vii) as a result of the above, Pronai's business prospects were far worse than represented; and (viii) Pronai lacked sufficient internal controls.

151. The Individual Defendants also purportedly warned investors of the risks it faced if PNT2258 was unsuccessful, stating in relevant part:

> Our business and future success depends on our ability to successfully develop, obtain regulatory approval for and commercialize our only clinical product candidate, PNT2258, which is at an early stage of development.
>
> * * *
>
> If clinical trials of PNT2258 or future product candidates that we may develop fail to demonstrate safety and efficacy or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of PNT2258 or future product candidates.

152. These warnings were materially false and misleading when made however, because at the time that Defendants made the purported warnings, Pronai was in possession of clinical trial data showing that PNT2258 was failing to meet its efficacy endpoints and as a result, would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL. Accordingly, the very risks Defendants were warning investors about had already materialized.

B. False and Misleading Statements Concerning the Potential Market for PNT2258

153. In the 2015 Second Quarter Report, Defendants falsely represented that Pronai would be "a leader in developing and commercializing a broad and diverse portfolio of cancer therapies and deliver therapeutic outcomes that dramatically changed patients' lives."

154. According to Defendants, based on PNT2258's supposed efficacy data, the Company was pursuing a broad strategy wherein PNT2258 would provide the "foundation for a "global registration strategy:"

> We have conducted two ***clinical*** trials with PNT2258 to date: a Phase 1 safety trial in patients with relapsed or refractory solid tumors and a Phase 2 trial in patients with relapsed or refractory NHL. ***Having observed preliminary evidence of efficacy and tolerability,*** we plan to pursue a broad registration-oriented clinical development program, initially in hematologic malignancies, that we anticipate will provide the foundation of ***a global registration strategy for PNT2258***.

(Emphasis added).

155. Defendants also falsely assured investors that the Company had a "multi-faceted clinical development strategy" that would maximize PNT2258's potential market:

> Our lead DNAi product candidate, PNT2258, targets BCL2, a widely overexpressed oncogene that is an important gatekeeper of the programmed cell death process known as apoptosis and has been linked to many forms of cancer. ***We are pursuing a multi-faceted clinical development strategy that is designed to efficiently achieve regulatory approval and maximize the commercial opportunity of PNT2258***.

156. The above statements were materially false and misleading when made because: (i) ongoing studies and internal Company experiments demonstrated DNAi and PNT2258 were ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; (iii) efficacy data from the ongoing Wolverine trial showed patients were not responding to treatment with PNT2258 and, thus, the potential market for PNT2258 was significantly less than represented or nonexistent; (iv) PNT2258 would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL, and the Company would soon abandon its corporate development strategy; (v) the Company had materially overstated the efficacy of PNT2258 and its business prospects; and (vi) as a result of the above, Pronai's business prospects were far worse than represented.

C. Materially False and Misleading Statements Concerning Pronai's Compliance with FDA Regulations

157. The 2015 Second Quarter Report contained numerous false representations and purported warnings to investors regarding the Company's compliance with FDA regulations and the risks associated thereto. For example, the Individual Defendants purportedly warned investors of the risks Pronai faced in connection with FDA oversight of the Wolverine and Brighton trials, stating that "[w]e may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed:"

> Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the study sites where the clinical trials are conducted…***Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including***:
>
> - ***deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols***;
> - deficiencies in the clinical trial operations or trial sites;
> - the product candidate may have unforeseen adverse side effects;
> - ***deficiencies in the trial design necessary to demonstrate efficacy***;
> - ***fatalities or other AEs arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;***
> - ***the product candidate may not appear to be more effective than current therapies***; or
> - the quality or stability of the product candidate may fall below acceptable standards.
>
> Although we have never been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial, ***if we elect or are forced to suspend or terminate a clinical trial of any other of our product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners***.

(Emphasis added).

158. The above statements were materially false and misleading when made because: (i) Pronai was implementing numerous protocol amendments to manipulate the Wolverine efficacy data and report successful trial results; (ii) Pronai planned to exclude the sickest patients in the Wolverine study from the efficacy data ultimately announced in June 2016; (iii) as a result, Pronai was not in compliance with FDA regulations and PNT2258 would never be an approved therapy for patients with relapsed or refractory DLBCL and/or RCLL.

III. MATERIALLY FALSE AND MISLEADING STATEMENTS IN PRONAI'S 2015 THIRD QUARTER REPORT

159. On November 5, 2015, the Company filed its quarterly report on Form 10-Q for the third quarter ended September 30, 2015 ("2015 Third Quarter Report") with the SEC, which was signed and certified by Individual Defendant Glover. The 2015 Third Quarter Report contained several categories of materially false and misleading statements relating to: (i) the efficacy of PNT2258 and the DNAI platform; (ii) the potential market for PNT2258 and the DNAI platform; (iii) the Company's compliance with FDA regulations; and (iv) Pronai's internal controls.

A. False and Misleading Statements Concerning the Efficacy of, and Potential Market for, PNT2258

160. In the 2015 Third Quarter Report, Defendants falsely represented that PNT2258 had produced "evidence of efficacy and tolerability" that would provide the "foundation for a "global registration strategy:"

> We have conducted two clinical trials with PNT2258 to date: a Phase 1 safety trial in patients with relapsed or refractory solid tumors and a Phase 2 trial in patients with relapsed or refractory non-Hodgkin's lymphoma (NHL). ***Having observed preliminary evidence of efficacy and tolerability, we plan to pursue a broad registration-oriented clinical development program, initially in hematologic malignancies, that we anticipate will provide the foundation of a global registration strategy for PNT2258***.

(Emphasis added)

161. Defendants further represented that Pronai was pursuing a broad strategy that would maximize the commercial opportunity of PNT2258:

> Our lead DNAi product candidate, PNT2258, targets BCL2, a widely overexpressed oncogene that is an important gatekeeper of the programmed cell death process known as apoptosis and has been linked to many forms of cancer. ***We are pursuing a multi-faceted clinical development strategy that is designed to efficiently achieve regulatory approval and maximize the commercial opportunity of PNT2258***.

162. The above statements were materially false and misleading when made because: (i) ongoing studies and internal Company experiments demonstrated DNAi and PNT2258 were ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; (iii) efficacy data from the ongoing Wolverine trial showed patients were not responding to treatment with PNT2258 and, thus, the potential market for PNT2258 was significantly less than represented or nonexistent; (iv) PNT2258 would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL, and the Company would soon abandon its corporate development strategy; (v) the Company had materially overstated the efficacy of PNT2258 and its business prospects; and (vi) as a result of the above, Pronai's business prospects were far worse than represented.

163. The Individual Defendants purportedly warned investors of the risks it faced if PNT2258 was unsuccessful stating for example that "our business is highly dependent on the success of our only clinical product candidate, PNT2258. If we are unable to successfully develop, obtain regulatory approval for and commercialize PNT2258, or experience significant delays in doing so, our business will be materially harmed:"

> Our business and future success depends on our ability to successfully develop, obtain regulatory approval for and commercialize our only clinical product candidate, PNT2258, which is at an early stage of development.
>
> If clinical trials of PNT2258 or future product candidates that we may develop fail to demonstrate safety and efficacy or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of PNT2258 or future product candidates.

164. These purported warnings were materially false and misleading because, at the time that Defendants made these purported warnings, Pronai was in possession of clinical trial data showing that PNT2258 was failing to meet its efficacy endpoints and as a result, would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL. Accordingly, the very risks Defendants were warning investors about had already materialized.

B. Materially False and Misleading Statements Concerning Pronai's Compliance with FDA Regulations

165. The 2015 Third Quarter Report incorporated by reference the numerous false representations and purported warnings to investors regarding the Company's compliance with FDA regulations and the risks associated thereto that were previously included in the Company's 2015 Second Quarter Report. For example, the 2015 Third Quarter report incorporated by reference that the Individual Defendants had purportedly warned investors of the risks Pronai faced in connection with FDA oversight of the Wolverine and Brighton trials, stating that "[w]e may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed:"

> Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the study sites where the clinical trials are conducted…***Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including***:

- ***deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols***;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- ***deficiencies in the trial design necessary to demonstrate efficacy***;
- ***fatalities or other AEs arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;***
- ***the product candidate may not appear to be more effective than current therapies***; or
- the quality or stability of the product candidate may fall below acceptable standards.

Although we have never been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial, ***if we elect or are forced to suspend or terminate a clinical trial of any other of our product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners***.

(Emphasis added).

166. The above statements were materially false and misleading when made because: (i) Pronai was implementing numerous protocol amendments to manipulate the Wolverine efficacy data and report successful trial results; (ii) Pronai planned to exclude the sickest patients in the Wolverine study from the efficacy data ultimately announced in June 2016; (iii) as a result, Pronai was not in compliance with FDA regulations and PNT2258 would never be an approved therapy for patients with relapsed or refractory DLBCL and/or RCLL.

C. Materially False and Misleading Statements Concerning Pronai's Internal Controls

167. The 2015 Third Quarter Report also contained numerous false representations and purported warnings to investors regarding the Company's implementation and maintenance of effective internal controls. Specifically, the Defendants assured investors that: "***our Chief***

Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of September 30, 2015 to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosures." (Emphasis added).

168. The Defendants also represented that Pronai management had "implemented changes to our disclosure controls and procedures and internal control over financial reporting to remediate the material weakness identified," stating in more detail:

> In connection with the preparation of our consolidated financial statements for the years ended December 31, 2013 and 2014, our independent registered public accounting firm identified a material weakness in our internal control over financial reporting with respect to having sufficiently qualified accounting personnel to account for unusual and complex transactions in a timely manner, provide for the appropriate segregation of duties, review financial reporting data and account reconciliation, and perform a formal risk assessment for our company.
>
> ***We have implemented changes to our disclosure controls and procedures and internal control over financial reporting to remediate the material weakness identified above. We have strengthened the operation of our internal controls over the accounting for non-routine, complex transactions, including increasing the depth and experience within our accounting and finance organization, as well as designing and implementing improved processes and internal controls to identify such matters. We have hired additional personnel to build our financial management and reporting infrastructure, including a Chief Financial Officer. We believe that the remediation initiative outlined above was sufficient to remediate the material weakness in internal control over financial reporting as discussed above***, however, the material weakness will not be considered remediated until the applicable internal controls operate for a sufficient period of time and management has concluded, through testing, that these controls are consistently operating effectively.

(Emphasis added).

169. The above statements were materially false and misleading when made because Pronai's internal controls were deficient and, thus, allowed the Company to: (i) misrepresent the efficacy of its clinical trials; (ii) violate FDA regulations; and (iii) violate the Company's own internal policies related to its "code of business conduct and ethics" and "precautions [] to detect and prevent inappropriate conduct."

170. Throughout the Class Period, the above material misstatements served to maintain the Company's inflated stock price. Indeed, as a result of the above misstatements, Pronai's stock price increased 11.5% from $17.46 per share on November 5, 2015 to $19.47 per share on November 9, 2015.

IV. MATERIALLY FALSE AND MISLEADING STATEMENTS IN PRONAI'S NOVEMBER 19, 2015 PRESENTATION

171. On November 19, 2015, Individual Defendant Glover presented an overview of the Company at the Jefferies Autumn 2015 Global Healthcare Conference in London. The conference was specifically designed to target institutional, private equity and venture capital investors and solicit near and long-term investment opportunities in the Company.

172. To that end, Defendant Glover presented a 36-page presentation touting the Company's "[n]oval [DNAi] platform" and the positive "efficacy and durability" of PNT2258 in the "investment highlights" on page 1:

- Novel platform with pipeline potential: Pioneering a novel class of therapeutics based on our proprietary DNA interference (DNAi) platform focused on high value genetic targets in oncology

- Phase 2 asset targeting BCL2 oncogene: Clinical data to date for lead product candidate, PNT2258, demonstrates single agent efficacy and durability with a well-tolerated safety profile

173. Also in the investment highlights, Defendants assured investors that PNT2258 had "[b]road commercial potential" for many therapies:

- Multiple, meaningful data catalysts: Planned initiation of six Phase 2 trials of PNT2258, beginning with third line relapsed or refractory DLBCL and Richter's transformed CLL, with multiple clinical readouts anticipated over the next 12-24 months

- Broad commercial potential as mono-/combo- therapy: BCL2 implicated in broad range of hematological malignancies and solid tumors. Augmentation of apoptotic signaling via BCL2 with a well-tolerated agent may lead to numerous combination options

174. The presentation further described PNT2258's "***[s]ignificant commercial potentia***l: BCL2 expressed in ~60% of top 10 cancers," and the Company's "broad registration-oriented development strategy for PNT2258" which included "***additional combination and monotherapy trials planned for 2016 [and] a long-term strategy to maximize global commercial value, include sold tumors***." (Emphasis added).

175. In addition, the presentation touted the Company's "unique and distinct" DNAi technology as "allow[ing] for a more profound impact on oncogenic targets" and "complementary to other therapeutic approaches."

176. The above statements were materially false and misleading when made because: (i) ongoing studies and internal Company experiments demonstrated DNAi and PNT2258 were ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; (iii) efficacy data from the ongoing Wolverine trial showed patients were not responding to treatment with PNT2258 and, thus, the potential market for PNT2258 was significantly less than represented or nonexistent; (iv) PNT2258 would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL, and the Company would soon abandon its corporate development strategy; (v) the Company had materially overstated the efficacy of PNT2258 and its

business prospects; (vi) as a result of the above, Pronai's business prospects were far worse than represented; and (vii) Pronai lacked sufficient internal controls.

177. Throughout the Class Period, the above material misstatements served to maintain the Company's inflated stock price. Indeed, as a result of the above misstatements, Pronai's stock price increased 3.5% from $17.52 per share on November 19, 2015 to $18.13 per share on November 23, 2015.

V. MATERIALLY FALSE AND MISLEADING STATEMENTS IN PRONAI'S JANUARY 14, 2016 PRESENTATION

178. On January 14, 2016, Individual Defendant Glover presented an overview of the Company at the JP Morgan 2016 Healthcare Conference in San Francisco. The conference was specifically designed to target institutional, private equity and venture capital investors and solicit near and long-term investment opportunities in the Company. To that end, Defendant Glover presented a 28-page presentation which lauded the purported efficacy and potential market for PNT2258 on page 4 of the "investment highlights" of the presentation:

- Phase 2 DNAi asset targeting BCL2 oncogene:
    - ***Clinical data: In pilot Phase 2 study, PNT2258, demonstrates single agent efficacy*** and durability with a well-tolerated safety profile
    - ***Multiple, meaningful data catalysts: Planned initiation of six Phase 2 trials of PNT2258, beginning with third line relapsed or refractory DLBCL and Richter's transformed CLL, with multiple clinical readouts anticipated over the next 24 months***
    - ***Broad commercial potential as mono-/combo-therapy***: BCL2 implicated in broad range of hematological malignancies and solid tumors. Augmentation of apoptotic signaling via BCL2 with a well-tolerated agent may lead to numerous combination options

- ***Novel platform: Potential for a pipeline of novel therapeutics based on proprietary DNA interference (DNAi) platform focused on high value genetic targets in oncology***

(Emphasis added).

179. The presentation continued on to describe PNT2258's "***[s]ignificant commercial potential,***" including "***four additional combination and monotherapy trials planned for 2016 [and] a long-term strategy to maximize global commercial value, include sold tumors***." (Emphasis added).

180. The above statements were materially false and misleading when made because: (i) ongoing studies and internal Company experiments demonstrated DNAi and PNT2258 were ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; (iii) efficacy data from the ongoing Wolverine and Brighton trials showed enrolled patients were not responding to treatment with PNT2258; (iv) as a result, Pronai was implementing numerous protocol amendments to manipulate the Wolverine and Brighton efficacy data and report successful trial results; (v) PNT2258 would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL, and the Company would never submit an NDA to the FDA for either indication; (vi) the Company had materially overstated the efficacy of PNT2258 and its business prospects; (vii) as a result of the above, Pronai's business prospects were far worse than represented; and (viii) Pronai lacked sufficient internal controls.

VI. MATERIALLY FALSE AND MISLEADING STATEMENTS IN PRONAI'S 2015 ANNUAL REPORT

181. On March 3, 2016, Pronai filed its 2015 Annual Report on Form 10-K with the SEC, which was signed and certified by Individual Defendants Glover and Jagpal. The 2015 Annual Report contained several categories of materially false and misleading statements

concerning: (i) the efficacy of PNT2258 and the DNAI platform; (ii) the potential market for PNT2258 and the DNAI platform; (iii) the Company's compliance with FDA regulations; and (iv) Pronai's internal controls.

A. False and Misleading Statements Concerning the Efficacy of PNT2258 and the DNAi Platform

182. In the 2015 Annual Report, Defendants falsely represented that PNT2258 had produced "evidence of efficacy and tolerability" and would treat "a variety of oncology indications:"

> Our lead product candidate, PNT2258, is based on our proprietary DNA interference (DNAi) technology platform. PNT2258 is designed to target BCL2, a widely overexpressed oncogene that is an important gatekeeper of the programmed cell death process known as apoptosis and has been linked to many forms of cancer. In a recent single-agent Phase 2 trial of 13 patients with relapsed or refractory non-Hodgkin's lymphoma (NHL), PNT2258 demonstrated evidence of anti-tumor activity, with ***11 patients achieving a complete response (CR), partial response (PR) or stable disease (SD). Furthermore, all four of the diffuse large B-cell lymphoma (DLBCL) patients treated in this trial experienced a clinical response, including three CRs and one PR***, with reported durations on study in the range of nine to more than 28 months. Although not statistically powered for a formal efficacy analysis, ***we believe the preliminary evidence of efficacy observed in this trial, coupled with safety and tolerability data collected to date, suggest that PNT2258 has potential in the treatment of a variety of oncology indications***.

(Emphasis added).

183. With respect to the Wolverine trial specifically, Defendants falsely represented that the trial results would support further trials, stating: "***We expect that the results of this trial may ultimately be used to design a subsequent registration trial***." (Emphasis added).

184. Defendants also continued to tout PNT2258's unique ability to treat DLBCL patients, stating in relevant part: "Wolverine has also been designed to identify patient responders according to the genetics of their DLBCL cancer cells, specifically the cell-of-origin sub-type (germinal center B-cell (GCB) vs. activated B-cell (ABC)), as these patients tend to differ in their prognoses and response to medical treatment. Since BCL2 is overexpressed in both sub-types,

PNT2258 may be active in both types of disease, which could potentially differentiate our drug versus certain other therapeutics in common use or in development that only demonstrate activity in one sub-type." (Emphasis added).

185. The above statements were materially false and misleading when made because: (i) ongoing studies and internal Company experiments demonstrated DNAi and PNT2258 were ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; (iii) efficacy data from the ongoing Wolverine and Brighton trials showed enrolled patients were not responding to treatment with PNT2258; (iv) as a result, Pronai was implementing numerous protocol amendments to manipulate the Wolverine and Brighton efficacy data and report successful trial results; (v) PNT2258 would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL, and the Company would never submit an NDA to the FDA for either indication; (vi) the Company had materially overstated the efficacy of PNT2258 and its business prospects; (vii) as a result of the above, Pronai's business prospects were far worse than represented; and (viii) Pronai lacked sufficient internal controls.

186. Defendants also purportedly warned investors of the risks it faced if PNT2258 was unsuccessful stating for example that "our business is highly dependent on the success of our only clinical product candidate, PNT2258. If we are unable to successfully develop, obtain regulatory approval for and commercialize PNT2258, or experience significant delays in doing so, our business will be materially harmed:"

> Our business and future success depends on our ability to successfully develop, obtain regulatory approval for and commercialize our only clinical product candidate, PNT2258, which is at an early stage of development.

* * *

> If clinical trials of PNT2258 or future product candidates that we may develop fail to demonstrate safety and efficacy or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of PNT2258 or future product candidates.

187. These purported warnings were materially false and misleading because, at the time that Defendants made these purported warnings, Pronai was in possession of clinical trial data showing that PNT2258 was failing to meet its efficacy endpoints and as a result, would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL Accordingly, the very risks Defendants were warning investors about had already materialized.

B. False and Misleading Statements Concerning the Market for PNT2258

188. In the 2015 Annual Report, Defendants falsely represented that Pronai was poised to become "a leader in developing and commercializing a broad and diverse portfolio of cancer therapies and deliver therapeutic outcomes that dramatically changed patients' lives." In particular, with respect to the Company's development strategy for PNT2258, its "lead product candidate", Defendants represented:

> **Our Strategy**
>
> Key elements of our business strategy are to:
>
> - ***Expedite the Clinical Development and Regulatory Approval of PNT2258***. ***We plan to advance our lead product candidate, PNT2258, for the treatment of several hematologic malignancies, initially focusing on indications where we believe PNT2258 has demonstrated anti-tumor activity and where there are significant unmet medical needs***. The first two indications we plan to pursue are in DLBCL and Richter's CLL. In December 2014, we initiated Wolverine, a Phase 2 trial for the treatment of third-line relapsed or refractory DLBCL, and in October 2015, we initiated Brighton, a Phase 2 trial for the treatment of Richter's CLL. ***We are also designing a number of additional Phase 2 trials that could support the registration and commercialization strategies for PNT2258. If the data obtained in any of these trials are highly compelling, we plan to discuss accelerated registration paths and other regulatory designations with regulatory agencies***.

* * *

- Pursue a Multi-Faceted Development Strategy for PNT2258 Across Many Oncology Indications. In addition to developing PNT2258 for DLBCL and Richter's CLL, we intend to expand the commercial market opportunity for PNT2258 by developing it for the treatment of a wide variety of BCL2-driven tumors, such as leukemias or solid tumors, as monotherapy and in combination with other therapeutic agents or treatment regimens. BCL2 overexpression has also been implicated as a driver of a wide variety of solid tumors, including breast, prostate and lung, which could provide additional future development opportunities for PNT2258.

- Continue to Invest in our Proprietary DNAi Technology Platform and Evaluate its Potential to Yield Additional Pipeline Products. We plan to continue to conduct research in the field of DNAi to further our understanding of the anti-cancer mechanism of action of this technology. We believe DNAi technology may be applicable to additional high value genetic targets beyond BCL2 that are also challenging to effectively drug by conventional means . . . .

(Emphasis added).

189. Regarding the potential market for PNT2258, Defendants claimed that PNT2258 would be ***"develop[ed] . . . across a variety of oncology indications:"***

> We plan to advance our lead product candidate, PNT2258, for the treatment of several hematologic malignancies, initially focusing on indications where we believe PNT2258 has demonstrated anti-tumor activity and where there are significant unmet medical needs. The first two indications we plan to pursue are in DLBCL and Richter's CLL.

(Emphasis added).

190. Moreover, according to Defendants, based on PNT2258's supposed efficacy data, the Company was pursuing a broad strategy wherein PNT2258 would provide the "foundation for a "global registration strategy:"

> ***We are pursuing a multi-faceted clinical development strategy that is designed to achieve regulatory approval and maximize the commercial opportunity of PNT2258***. We have conducted two clinical trials with PNT2258 to date: a Phase 1 safety trial in patients with relapsed or refractory solid tumors and a Phase 2 trial in patients with relapsed or refractory NHL. ***Having observed preliminary evidence of efficacy and tolerability, we plan to pursue a broad registration-oriented clinical development program, initially in***

> ***hematologic malignancies, that we anticipate will provide the foundation of a global registration strategy for PNT2258***.

(Emphasis added).

191. In touting PNT2258 as its "lead drug product," Defendants represented that PNT2258 could be used in other therapies:

> [T]he "***primary goal of our clinical development strategy is to exploit the full commercial potential of PNT2258 by developing the product candidate in earlier lines of therapy in DLBCL and additional indications***, either as monotherapy or in combination with other therapeutic agents or treatment regimens. Specifically, we believe that ***PNT2258 could also potentially amplify and be complementary to other therapeutic modalities***." In light of this "primary goal" the Company reiterated that it planned "to initiate additional Phase 2 trials with PNT2258 in combination with other therapeutic agents or treatment regiments" and "plan to discuss accelerated registration paths and other regulatory designations with regulatory agencies.

(Emphasis added).

192. The 2015 Annual Report further assured investors that there was "strong scientific rationale" to support the clinical development of PNT2258 in various Phase 2 trials, stating in relevant part:

> [T]here is a ***scientific rationale*** to enhance the apoptotic signal with the addition of PNT2258 to these targeted therapies. We believe there is a ***strong scientific rationale*** to suggest that targeting BCL2 could be clinically beneficial in combination with a targeted therapy and may initiate a Phase 2 combination trial of PNT2258 in combination with a targeted therapy…We may initiate a trial to test the potential efficacy of PNT2258 as a single agent in the treatment of one or more other hematological malignancies.

(Emphasis added).

193. With respect to the DNAi platform, Defendants represented that "DNAi technology may be applicable to additional high value genetic targets beyond BCL2 that are also challenging to drug by conventional means."

194. The above statements were materially false and misleading when made because: (i) ongoing studies and internal Company experiments demonstrated DNAi and PNT2258 were

ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; (iii) efficacy data from the ongoing Wolverine and Brighton trials showed patients were not responding to treatment with PNT2258 and, thus, the potential market for PNT2258 was significantly less than represented or nonexistent; (iv) PNT2258 would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/ RCLL, and the Company would soon abandon its corporate development strategy; (v) the Company had materially overstated the efficacy of PNT2258 and its business prospects; (vi) as a result of the above, Pronai's business prospects were far worse than represented; and (vii) Pronai lacked sufficient internal controls.

C. False and Misleading Statements Concerning Pronai's Compliance with FDA Regulations

195. The 2015 Annual Report also included numerous false representations and purported warnings to investors regarding the Company's compliance with FDA regulations and the risks associated thereto. For example, the Individual Defendants purportedly warned investors of the risks Pronai faced in connection with FDA oversight of the Wolverine and Brighton trials, stating that "[w]e may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed:"

> Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the study sites where the clinical trials are conducted…***Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including***:
>
> - ***deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols***;
> - deficiencies in the clinical trial operations or trial sites;
> - the product candidate may have unforeseen adverse side effects;
> - ***deficiencies in the trial design necessary to demonstrate efficacy***;

- ***fatalities or other AEs arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;***
- ***the product candidate may not appear to be more effective than current therapies***; or
- the quality or stability of the product candidate may fall below acceptable standards.

Although we have never been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial, ***if we elect or are forced to suspend or terminate a clinical trial of any other of our product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners***.

(Emphasis added).

196. The above statements and purported warnings were materially false and misleading when made because: (i) Pronai was implementing numerous protocol amendments to manipulate the Wolverine efficacy data and report successful trial results; (ii) Pronai planned to exclude the sickest patients in the Wolverine study from the efficacy data ultimately announced in June 2016; (iii) as a result, Pronai was not in compliance with FDA regulations and PNT2258 would never be an approved therapy for patients with relapsed or refractory DLBCL and/or RCLL.

D. False and Misleading Statements Concerning Pronai's Internal Controls

197. Each of Pronai's annual and quarterly filings with the SEC included certifications signed by the Individual Defendants, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, which represented that Pronai's financial statements did not contain material misstatements or omissions, and that the Company employed internal disclosure controls over financial reporting and related disclosures.

198. In this regard, the 2015 Annual Report contained a certification signed by Individual Defendant Glover, which stated:

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nick Glover, certify that:

1. I have reviewed this annual report on Form 10-K of ProNAi Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 3, 2016

/s/ Nick Glover
Nick Glover
President and Chief Executive Officer
(Principal Executive Officer*)*

199. The 2015 Annual Report contained a separate certification signed by Individual Defendant Jagpal, which contained a verbatim reproduction of Glover's certification statement above.

200. Moreover, the 2015 Annual Report contained certifications pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002, signed by Individual Defendant Glover, which stated:

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

I, Nick Glover, President and Chief Executive Officer of ProNAi Therapeutics, Inc. (Company), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- the Annual Report on Form 10-K of the Company for the year ended December 31, 2015 (Report), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: March 3, 2016

/s/ Nick Glover
Nick Glover
President and Chief Executive Officer
(Principal Executive Officer*)*

201. The 2015 Annual Report contained an identical certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, signed by Individual Defendant Jagpal.

202. The above certifications were materially false and misleading at the time they were made because Pronai's internal controls were deficient and, thus, allowed the Company to: (i) misrepresent the efficacy of its clinical trials; (ii) violate FDA regulations; and (iii) violate the Company's own internal policies related to its "code of business conduct and ethics" and "precautions [] to detect and prevent inappropriate conduct."

203. The 2015 Annual Report also contained numerous false representations and purported warnings to investors regarding the Company's implementation and maintenance of effective internal controls. Specifically, the Defendants assured investors that "our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2015, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level:"

> As of December 31, 2015, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. ***Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2015, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level***.

(Emphasis added).

204. The Defendants also represented that Pronai management had "devote[d] a substantial amount of time" to ensure the Company's "establishment and maintenance of effective disclosure and financial controls and corporate governance practices," stating in more detail:

> As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the stock exchange upon which our common stock is listed and other applicable securities rules and regulations ***impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives***…
>
> To achieve compliance with Section 404 within the prescribed period, ***we will be engaged in a process to document and evaluate our internal control over financial reporting***, which is both costly and challenging. In this regard, ***we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting***.

(Emphasis added).

205. The above material misstatements served to maintain the Company's inflated stock price. Indeed, as a result of the above misstatements, Pronai's stock price increased 9.36% from $6.41 per share on March 3, 2016 to $7.01 per share on March 7, 2016.

VII. MATERIALLY FALSE AND MISLEADING STATEMENTS IN PRONAI'S MARCH 3, 2016 PRESS RELEASE

206. Also on March 3, 2015, Pronai issued a press release announcing its financial and operational results for the year ended December 2015. Touting the efficacy of PNT2258, the Company's plans to initiate additional Phase 2 trials of PNT2258 in 2016, and the opportunities

associated with Pronai's unique DNAi platform, Individual Defendant Glover was quoted as stating:

> During 2015, we continued to transform ProNAi into a world-class oncology drug development company, securing both the talent and capital required to pursue our vision of developing and commercializing a pipeline of promising clinical-stage oncology assets with the potential to provide meaningful therapeutic outcomes to patients with cancer. Concurrent with building our company, ***we continued to advance our lead asset PNT2258, operationalizing two Phase 2 trials in 2015, Wolverine and Brighton, that are at the forefront of a concerted registration-oriented clinical development program planned for the drug***. In addition to PNT2258, during 2015 we began evaluating novel product candidates available for licensing or acquisition, with the goal of maximizing our clinical development capabilities and leveraging the full potential of our team by advancing a broad and diversified pipeline of assets.
>
> We anticipate reporting initial interim data from the Wolverine trial in third-line DLBCL in the second quarter of 2016. This trial has been designed to identify and characterize patient populations who respond to PNT2258 on the basis of their genetics and disease characteristics and will be essential to determining potential paths to registration for the drug. We recently started enrolling the Brighton trial in Richter's transformation and expect to report interim data from this trial before the end of 2016. ***We are also designing a number of additional Phase 2 trials that could support the registration and commercialization strategies for PNT2258. Two planned trials, Cypress and Granite, will evaluate PNT2258 in combination with standard-of-care treatment regimens for the treatment of second-line DLBCL in the "transplant eligible" and "transplant ineligible" patient populations respectively. We are also designing trials evaluating PNT2258's potential in DLBCL in combination with a targeted anti-cancer drug, and in other hematological malignancies as well***. . . .

(Emphasis added).

207. The above statements were materially false and misleading when made because: (i) ongoing studies and internal Company experiments demonstrated DNAi and PNT2258 were ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; (iii) efficacy data from the ongoing Wolverine and Brighton trials showed patients were not responding to treatment with PNT2258 and, thus, the potential market for PNT2258 was significantly less than

represented or nonexistent; (iv) Pronai was implementing undisclosed protocol amendments to manipulate the Wolverine and Brighton efficacy data and conceal the true results from two failing trials; (v) PNT2258 would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL, and the Company would soon abandon its corporate development strategy; (vi) the Company had materially overstated the efficacy of PNT2258 and its business prospects; and (vii) as a result of the above, Pronai's business prospects were far worse than represented.

208. The above material misstatements served to maintain the Company's inflated stock price. Indeed, as a result of the above misstatements, Pronai's stock price increased 9.36% from $6.41 per share on March 3, 2016 to $7.01 per share on March 7, 2016.

VIII. MATERIALLY FALSE AND MISLEADING STATEMENTS IN PRONAI'S 2016 FIRST QUARTER REPORT

209. On May 10, 2016, the Company filed its quarterly report on Form 10-Q with the SEC for the first quarter of 2016 for the period ended March 31, 2016 ("2016 First Quarter Report"), which was signed and certified by Individual Defendants Glover and Jagpal. The 2016 First Quarter Report contained several categories of materially false and misleading statements relating to: (i) the efficacy of PNT2258 and the DNAI platform; (ii) the potential market for PNT2258 and the DNAI platform; (iii) the Company's compliance with FDA regulations; and (iv) internal controls.

A. Materially False and Misleading Statements Concerning PNT2258's Efficacy

210. In the 2016 First Quarter Report, Defendants falsely represented that PNT2258 had produced "evidence of efficacy and tolerability," which would form the "***foundation of a global registration strategy for PNT225***:"

> We have conducted two clinical trials with PNT2258 to date: a Phase 1 safety trial in patients with relapsed or refractory solid tumors and a Phase 2 trial in patients with relapsed or refractory non-Hodgkin's lymphoma (NHL). ***Having observed preliminary evidence of efficacy and tolerability, we plan to pursue a broad registration-oriented clinical development program, initially in hematologic malignancies, that we anticipate will provide the foundation of a global registration strategy for PNT2258***.

211. The above statements were materially false and misleading when made because: (i) ongoing studies and internal Company experiments demonstrated DNAi and PNT2258 were ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; (iii) efficacy data from the ongoing Wolverine and Brighton trials showed patients were not responding to treatment with PNT2258 and, thus, the potential market for PNT2258 was significantly less than represented or nonexistent; (iv) Pronai was implementing undisclosed protocol amendments to manipulate the Wolverine and Brighton efficacy data and conceal the true results from two failing trials; (v) PNT2258 would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL, and the Company would soon abandon its corporate development strategy; (vi) the Company had materially overstated the efficacy of PNT2258 and its business prospects; and (vii) as a result of the above, Pronai's business prospects were far worse than represented.

212. The Individual Defendants also purportedly warned investors of the risks Pronai faced if PNT2258 was unsuccessful:

> Our business and future success depends on our ability to successfully develop, obtain regulatory approval for and commercialize our only clinical product candidate, PNT2258, which is at an early stage of development.
>
> * * *
>
> If clinical trials of PNT2258 or future product candidates that we may develop fail to demonstrate safety and efficacy or do not otherwise produce positive results, we

> may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of PNT2258 or future product candidates.

213. These purported warnings were materially false and misleading because, at the time that Defendants made these purported warnings, Pronai was in possession of clinical trial data showing that PNT2258 was failing to meet its efficacy endpoints and as a result, would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL. Accordingly, the very risks Defendants were warning investors about had already materialized.

214. Also on May 10, 2016, Pronai issued a press release announcing its financial and operational results for the first quarter of 2016. Touting the efficacy of PNT2258 and the Company's business prospects, Individual Defendant Glover was quoted as stating:

> ***During the first quarter, we continued to advance our lead cancer drug, PNT2258, in two Phase 2 trials, Wolverine and Brighton, and we remain on track to report interim data from the Wolverine trial in third-line diffuse large B-cell lymphoma (DLBCL) in June 2016***.

(Emphasis added).

215. The above statements were materially false and misleading when made because: (i) ongoing studies and internal Company experiments demonstrated DNAi and PNT2258 were ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; (iii) efficacy data from the ongoing Wolverine and Brighton trials showed patients were not responding to treatment with PNT2258 and, thus, the potential market for PNT2258 was significantly less than represented or nonexistent; (iv) Pronai was implementing undisclosed protocol amendments to manipulate the Wolverine and Brighton efficacy data and conceal the true results from two failing trials; (v) PNT2258 would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL, and the Company would soon abandon its corporate

development strategy; (vi) the Company had materially overstated the efficacy of PNT2258 and its business prospects; and (vii) as a result of the above, Pronai's business prospects were far worse than represented.

B. Materially False and Misleading Statements Concerning the Market for PNT2258

216. In the 2016 First Quarter Report, Defendants touted PNT2258's purported successful development and boasted that, through a "multi-faceted clinical development strategy that is designed to efficiently achieve regulatory approval and maximize the commercial opportunity of PNT2258," the Company would implement a "global registration strategy for PNT2258."

> We plan to pursue a broad registration-oriented clinical development program, initially in hematologic malignancies, that we anticipate will ***provide the foundation of a global registration strategy for PNT2258***.

(Emphasis added).

217. The above statements were materially false and misleading when made because: (i) ongoing studies and internal Company experiments demonstrated DNAi and PNT2258 were ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; (iii) efficacy data from the ongoing Wolverine and Brighton trials showed patients were not responding to treatment with PNT2258 and, thus, the potential market for PNT2258 was significantly less than represented or nonexistent; (iv) Pronai was implementing undisclosed protocol amendments to manipulate the Wolverine and Brighton efficacy data and conceal the true results from two failing trials; (v) PNT2258 would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL, and the Company would soon abandon its corporate development strategy; (vi) the Company had materially overstated the efficacy of PNT2258 and

its business prospects; and (vii) as a result of the above, Pronai's business prospects were far worse than represented.

C. Materially False and Misleading Statements Concerning Pronai's Compliance with FDA Regulations

218. The 2016 First Quarter Report also incorporated by reference the numerous false representations and purported warnings to investors regarding the Company's compliance with FDA regulations and the risks associated thereto originally included in the 2015 Annual Report. For example, the 2016 First Quarter Report incorporated by reference that the Individual Defendants purportedly warned investors of the risks Pronai faced in connection with FDA oversight of the Wolverine and Brighton trials, stating that "[w]e may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed:"

> Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the study sites where the clinical trials are conducted…***Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including***:
>
> - ***deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols***;
> - deficiencies in the clinical trial operations or trial sites;
> - the product candidate may have unforeseen adverse side effects;
> - ***deficiencies in the trial design necessary to demonstrate efficacy***;
> - ***fatalities or other AEs arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;***
> - ***the product candidate may not appear to be more effective than current therapies***; or
> - the quality or stability of the product candidate may fall below acceptable standards.
>
> Although we have never been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial, ***if we elect or are forced to suspend or terminate a clinical trial of any other of our product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or***

> ***eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners***.

(Emphasis added).

219. The above statements, incorporated by reference to the 2015 Annual Report, were materially false and misleading when made because: (i) Pronai was implementing numerous protocol amendments to manipulate the Wolverine efficacy data and report successful trial results; (ii) Pronai planned to exclude the sickest patients in the Wolverine study from the efficacy data ultimately announced in June 2016; (iii) as a result, Pronai was not in compliance with FDA regulations and PNT2258 would never be an approved therapy for patients with relapsed or refractory DLBCL and/or RCLL.

D. False and Misleading Statements Concerning Pronai's Internal Controls

220. The 2016 First Quarter Report also contained numerous false representations and purported warnings to investors regarding the Company's implementation and maintenance of effective internal controls. Specifically, the Defendants assured investors that "our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of March 31, 2016:"

> ***Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of March 31, 2016*** to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosures.

(Emphasis added).

221. The Defendants also represented that "[t]here were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended March 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting." (Emphasis added).

222. The above statements were materially false and misleading at the time they were made because Pronai's internal controls were deficient and, thus, allowed the Company to: (i) misrepresent the efficacy of its clinical trials; (ii) violate FDA regulations; and (iii) violate the Company's own internal policies related to its "code of business conduct and ethics" and "precautions [] to detect and prevent inappropriate conduct."

223. Throughout the Class Period, the above material misstatements served to maintain the Company's inflated stock price. Indeed, as a result of the above misstatements, Pronai's stock price increased 15.5% from $4.66 per share on May 9, 2016 to $5.38 per share on May 10, 2016.

THE TRUTH IS REVEALED

224. On June 6, 2016, the last day of the Class Period, Pronai announced interim data from the Wolverine Phase 2 trial of PNT2258 in patients with DLBCL including that the trial had failed to establish efficacy. According to Defendant Glover, "[a]lthough [Pronai] observed modest efficacy from PNT2258 in this interim analysis of Wolverine, [it does] not view these results as robust enough to justify continued development of the drug in DLBCL." As a result, Defendant Glover announced that Pronai would suspend all clinical development of PNT2258 – which, until three days prior, had been the Company's only drug in clinical development – and all further investment in the Company's DNAi platform.

225. The June 6, 2016 announcement also revealed *for the first time* that Pronai had implemented a protocol amendment to the Wolverine trial and would be ***excluding the trial's sickest patients from the efficacy results***, subtly revealing: "the Wolverine Phase 2 trial (PNT2258-03-DLBCL [NCT02226965]) is a multicenter, single-arm, open-label study of PNT2258 at a dose of 120 mg/m2 administered as a 4-hour IV infusion on days 1-5 of a 21-day cycle in adults with r/r FDG-PET positive, measureable DLBCL…***Following a protocol amendment***, enrollment was limited to patients with PS of 0-1 who had been exposed to 1-3 prior systemic regimens." (Emphasis added).

226. This was not the only revelation in the June 6, 2016 announcement, however. Pronai also revealed *for the first time* that the Brighton trial had managed to enroll only five patients in the trial since it was initiated eight months prior, and of these five patients, four had discontinued treatment and no responses had been observed in any patient to date. As a result, the Company was prematurely terminating the Brighton trial.

227. Finally, the June 6, 2016 presentation by Defendant Glover at the 2016 Annual Meeting of the American Society of Clinical Oncology disclosed *for the first time*, the final efficacy data from the Pilot Phase 2 trial that the Defendants had previously lauded as early as December 2014. Therein, Pronai finally disclosed that, although responses were observed in some patients treated with PNT2258, patients in the Pilot Phase 2 study actually experienced disease progression ***at a faster rate*** when being treated with PNT2258 than compared to their prior therapies. Further, of the 13 patients treated in the Pilot Phase 2 study, 12 discontinued treatment with PNT2258 as their disease progressed and 85% of the patients treated in the study experienced one or more grade three or four adverse event.

228. The June 6 press release also summarized the lackluster efficacy data from both the Wolverine and Brighton trials. With respect to the Wolverine trial, Pronai astoundingly revealed for the first time that *even excluding the sickest patients enrolled in the trial*: (i) 89% of the patients had discontinued treatment; (ii) all 37 subjects had experienced one or more adverse event; (iii) 65% of the subjects had experienced one or more grade three or four adverse event; (iv) 43% of the subjects had experienced a severe adverse event; and (v) 22% of the subjects had died within 30 days of their last dose of PNT2258. Based on these results, the Company concluded that: "[c]linical data in Wolverine are not trending to an outcome that supports the likelihood of registration as monotherapy in late line DLBCL."

229. With respect to the Brighton trial, the Company revealed for the first time that *inter alia*: (i) only five subjects had been enrolled in the trial to date, of which four had discontinued treatment; (ii) no responses were observed in any patient; (iii) two subjects discontinued study treatment due to death, with one patient dying on day 2 of the study and the other dying on day 28 of the study; and (iv) two other subjects discontinued treatment for progressive disease, i.e. because they got worse, after being treated with PNT2258. Based on these results, the Company concluded: "In the Brighton study…***we have also noted generally poor outcomes in this advanced patient population, with limited signs of activity***." (Emphasis added).

230. Upon this news, the price of Pronai common stock declined from a closing share price of $6.38 per share on June 3, 2016 to close at $2.07 per share on June 6, 2016 a loss of more than 67%, on extremely heavy trading volume.

POST-CLASS PERIOD EVENTS

231. Following the June 6 revelations, Pronai quickly shuttered its DNAi research facility in Plymouth, Michigan which had previously supported the clinical development of

PNT2258. Specifically, the Company announced on August 12, 2016 – only two months after the trials' results were revealed – that although it "continues to review the[] data in order to determine next steps with the asset and technology [] no further investment in PNT2258 or the underlying DNAi platform by ProNAi is contemplated and ***the company subsequently has closed its research facility based in Plymouth, Michigan, which supported these programs***." (Emphasis added).

232. According to the same August 12 press release, the Company's new corporate strategy was focused solely on the clinical development of AS-141 (referred to by Pronai as PNT141) – the alternative oncology drug Pronai announced it had acquired only three days before announcing the Wolverine and Brighton trial failures. In this regard, Defendant Glover explained the Company's new vision *for the first time* to investors:

> Our goal is to build a broad pipeline consisting primarily of assets that leverage discoveries on the leading edge of cancer biology. PNT141 highlights this strategy as Cdc7 has a central function in both DNA replication and DNA damage response, two mechanisms that are increasingly recognized as having critical roles in driving cancer. In addition to toxicology and manufacturing work, we are conducting a robust preclinical assessment of PNT141 aimed at further informing our clinical development plans and patient selection strategies as we prepare this product candidate for clinical trials.

233. Shortly thereafter, on January 9, 2017, Pronai announced that it had changed its corporate name to Sierra Oncology, Inc. and that its shares would begin trading on the NASDAQ under the symbol 'SRRA', effective on January 10th. According to Defendant Glover, the Company's new name reflected its evolution into an oncology focused company advancing an emerging pipeline of promising therapies that target the DNA Damage Response (DDR) network. To investors, however, this meant their Company had entirely abandoned the DNAi drug development platform, the only drug in clinical development, and the corporate identity that had been touted to them for years, in only a few short months.

PRONAI'S INTERNAL CONTROL VIOLATIONS

234. During the Class Period, Defendants falsely represented that Pronai maintained internal controls over financial reporting to ensure the reliability of the Company's financial reporting.

235. In addition, during the Class Period, Defendants concealed a chronic and systematic breakdown of the Company's internal accounting controls, thereby allowing the Company to, among other things, withhold and conceal the adverse clinical trial results from the Wolverine and Brighton Phase 2 trials, including the fact that the Individual Defendants had repeatedly manipulated the trial protocol in each trial. Defendants' lack of internal controls also allowed them to violate FDA regulations.

236. Defendants would eventually admit that the Company lacked internal controls in the 2015 Second Quarter Report stating: "In connection with the preparation of our 2013 and 2014 financial statements, ***our independent registered public accounting firm identified a material weakness in internal control over financial reporting*** with respect to having sufficiently qualified accounting personnel to account for unusual and complex transactions in a timely manner, provide for the appropriate segregation of duties, review financial reporting data and account reconciliation and perform a formal risk assessment for our company." (Emphasis added).

237. As a result of Defendants' failure to maintain effective internal controls, they were able to conceal the adverse clinical trial results and the Company's stock price remained artificially inflated throughout the Class Period.

238. As the SEC has explained, internal controls are fundamental and critical for summarizing and reporting financial data . . . ." 15 U.S.C. § 78m(b)(2).[38] Indeed, a lack of fundamental internal controls, as here, constitutes a "material weakness" that should be immediately disclosed to investors under GAAP.

239. Generally accepted auditing standards ("GAAS") set forth the role of a Company's management in an audit of an entity's financial statements. Specifically:

> [M]anagement and, when appropriate, those charged with governance, have responsibility
>
> a. for the preparation and fair presentation of the financial statements in accordance with the applicable financial reporting framework;
>
> b. for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error…[39]

240. The Individual Defendants were further required under Rule 302 of the Sarbanes-Oxley Act of 2002 to provide certifications relating to the company's internal controls over financial reporting in the False and Misleading Financial Statements.

241. Additionally, Section 302 of the Sarbanes-Oxley Act of 2002 required Defendants to maintain, assess and report on the effectiveness of the Company's internal control over financial reporting. The language provides the following, in relevant part:

> (a) REGULATIONS REQUIRED.—The Commission shall, by rule, require, for each company filing periodic reports under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m, 78o(d)), that the principal executive officer or officers and the principal financial officer or officers, or persons performing

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[38] Specifically, the SEC requires a public company to: (a) make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets of the issuer; and (b) devise and maintain a system of internal accounting controls . . . . " 15 U.S.C. § 78m(b)(2).

[39] AU-C Preface – *Principles Underlying an Audit Conducted in Accordance with Generally Accepted Auditing Standards*.

> similar functions, certify in each annual or quarterly report filed or submitted under either such section of such Act that—
>
> (1) the signing officer has reviewed the report;
>
> (2) based on the officer's knowledge, the report does not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which such statements were made, not misleading;
>
> (3) based on such officer's knowledge, the financial statements, and other financial information included in the report, fairly present in all material respects the financial condition and results of operations of the issuer as of, and for, the periods presented in the report;
>
> (4) the signing officers—
>
> (A) are responsible for establishing and maintaining internal controls;
>
> (B) have designed such internal controls to ensure that material information relating to the issuer and its consolidated subsidiaries is made known to such officers by others within those entities, particularly during the period in which the periodic reports are being prepared;
>
> (C) have evaluated the effectiveness of the issuer's internal controls as of a date within 90 days prior to the report; and
>
> (D) have presented in the report their conclusions about the effectiveness of their internal controls based on their evaluation as of that date…

242. Auditing standards established and adopted by the Public Company Accounting Oversight Board (the "PCAOB"), specifically Auditing Standard ("AS") No. 5, *An Audit of Internal Control over Financial Reporting that is Integrated with an Audit of Financial Statements and Related Independence Rules and Conforming Amendments* ("AS 5"), defines internal controls over financial reporting as follows:

> Internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial

> statements for external purposes in accordance with GAAP and includes those policies and procedures that –
>
> (1) Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
>
> (2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
>
> (3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.[40]

243. Professional accounting standards recognize that a company's control environment sets the tone of an *organization*, and is the foundation for all other components of internal control, providing discipline and structure. The Committee of Sponsoring Organizations of the Treadway Commission framework also discusses a Company's control environment as being one of five interrelated components of internal control, stating:

> Control environment. Senior management must set an appropriate "***tone at the top***" that positively influences the control consciousness of entity personnel. The control environment is the foundation for all other components of internal control and provides discipline and structure.

244. The Company's most senior executive management, comprised in substantial part of the Individual Defendants herein, embraced a "tone at the top" of ignoring and/or concealing PNT2258's clinical trial results demonstrating PNT2258 would never be an effective third-line therapy for patients with relapsed or refractory DLBCL and/or RCLL. The purported control environment created by the Individual Defendants allowed for the concealment of material

[40] AS 5, Appendix A, A-5.

information concerning the Company's core business (PNT2258) in order keep the Company's stock price artificially inflated throughout the Class Period.

245. Moreover, Defendants' failure to identify such control deficiencies (e.g., material weaknesses) within the Company rendered Defendants' Sarbanes Oxley reports in the False and Misleading Statements section materially false and misleading in turn, and contributed to the Company's issuance of materially false and misleading financial statements in violation of GAAS.

ADDITIONAL SCIENTER ALLEGATIONS

246. As alleged herein, each of the Individual Defendants acted with scienter in that they knew or recklessly disregarded that the public statements and documents issued and disseminated in the name of the Company were materially false and misleading, knew or acted with deliberate recklessness in disregarding that such statements and documents would be issued and disseminated to the investing public, and knowingly and substantially participated and/or acquiesced in the issuance or dissemination of such statements and documents as primary violators of the federal securities laws.

247. The Individual Defendants had the opportunity to commit and participate in the wrongful conduct complained of herein. Each was a senior executive officer and/or director of Pronai and thus controlled the information disseminated to the investing public in the Company's press releases and SEC filings. As a result, each could falsify the information that reached the public about the Company's business and performance.

248. Throughout the Class Period, each of the Individual Defendants acted intentionally or recklessly and participated in and orchestrated the fraudulent schemes alleged herein to conceal PNT2258's lack of efficacy and the failed Wolverine and Brighton trial results. Such actions allowed Defendants to cause the Company's stock price to be artificially inflated throughout the

Class Period. The Individual Defendants' scienter may be imputed to Pronai as the Individual Defendants were among the Company's most senior management and were acting within the scope of their employment.

I. THE INDIVIDUAL DEFENDANTS KNOWINGLY OR RECKLESSLY MISREPRESENTED PNT2258 AND THE DNAI PLATFORM'S EFFICACY AND THE FAILED WOLVERINE AND BRIGHTON TRIAL RESULTS

249. Prior to and throughout the Class Period, the Individual Defendants knew that the Company's purported "breakthrough" DNAi platform was not a viable technology and that PNT2258 would never be an effective third-line therapy to treat patients with relapsed or refractory DLBCL and RCLL as a evidenced by: (A) the fact that the PNT2258 clinical trials were all uncontrolled and unblinded and the Individual Defendants admittedly had access to, and did review, interim trial results demonstrating PNT2258 was failing to demonstrate efficacy in treating relapsed or refractory DLBCL and RCLL; (B) the protocol amendments that Defendants made to the Wolverine and Brighton trials, which were approved by Defendant Glover before their submission to the FDA; (C) Defendants' own internal studies and experiments, which showed DNAi was not "real" and PNT2258 was not an effective treatment, which were discussed at Company meetings attended by Defendants; (D) PNT2258 was Pronai's "lead drug product"; (E) the suspicious timing of the resignations of three members of the Board, the Chief Scientific Officer, and the Chief Medical Officer; and (F) the abrupt change in corporate strategy in December 2015 to effectively abandon DNAi and PNT2258.

A. Defendants' Direct Knowledge of Interim Results from the Phase 1, Phase 2 Pilot and Ongoing Wolverine and Brighton Trials

250. As discussed above, the Phase 1, Pilot Phase 2, Wolverine and Brighton trials were all open-label and uncontrolled such that the Company's key executive team, including the Individual Defendants, were able to, and admittedly did, access and synthesize data real-time as

the trials were ongoing. For example, Defendants made the following public admissions regarding their ongoing access and digestion of PNT2258 trial data months and even years in advance of the data's public disclosure:

- With respect to the Phase 1 dose-escalation study of PNT2258, although the Company did not publicly report data from the trial until December 5, 2012, in a March 15, 2012 interview with *BioWorld Today*, Pronai's then-CEO and Board member Mina Sooch revealed that "[e]arly Phase 1 data suggest[s] the trial will validate the company's preclinical studies of PNT2258."

- With respect to the Pilot Phase 2 study, although the Company did not publicly report interm data from the Phase 2 trial until December 5, 2014, Pronai's then-CEO Mina Sooch presented detailed safety and efficacy data as the trial was ongoing at the 55th Annual Meeting of the American Society for Hematology (ASH) on December 9, 2013 – an entire year earlier. In addition, Pronai's key executives (including Sooch, Chief Scientific Officer Wendi Rodrigueza, and Chief Medical Officer Richard A. Messmann) summarized the data from the ongoing Pilot Phase 2 study in a medical journal sponsored by the American Society for Hematology on November 15, 2013.

- With respect to the Wolverine trial, although the Company did not report interim trial data from the Wolverine study until June 6, 2016, Defendant Glover provided an update on the Company's ongoing clinical development of PNT2258 including the Wolverine trial at the 33rd Annual J.P. Morgan Healthcare Conference on January 15, 2015, more than a year before the interim data was publicly disclosed.

- With respect to the Brighton trial, although the Company did not have an interim analysis for the trial scheduled until year end 2016, it prematurely announced data from the trial when revealing the Wolverine trial had failed, on June 6, 2016 – nearly six months before the Company's scheduled interim look.

251. Moreover, Defendants conducted an interim analysis for all data collected in the Wolverine trial on April 25, 2016 for patients enrolled as of February 29, 2016. As Defendant Glover later disclosed only after the Class Period, this analysis showed indisputably that PNT2258 would fail to achieve its efficacy endpoints – regardless of how many times the Company manipulated them. In fact, after the Class Period, Defendant Glover described this interim data as "not trending to an outcome that supports the likelihood of registration" and not "robust enough to

justify continued development," yet during the Class Period continued to assure investors that PNT2258 would "change treatment paradigms across a wide range of oncology indications."

252. Moreover, Pronai was required under FDA regulations to monitor patient deaths and discontinuations, and report such events promptly to the FDA.

253. As a result of the above, Defendants were admittedly analyzing the PNT2258 clinical trial data in the Phase 1, Pilot Phase 2, Wolverine and Brighton trials as the trials were ongoing and thus, were aware that PNT2258 was not producing evidence of efficacy and would never be an effective therapy for relapsed or refractory DLBCL and/or RCLL.

B. Defendants Repeatedly Approved Undisclosed Protocol Amendments in the Wolverine and Brighton Trials in Order to Manipulate the Results So the Trial Would Not Fail

254. Prior to and throughout the Class Period, Pronai implemented numerous protocol amendments in both the Wolverine and Brighton trials that have not been disclosed to investors to this day. As discussed above, between December 28, 2014 and March 2016, Pronai repeatedly manipulated the outcome measures for the Wolverine and Brighton trials, with the first major amendment to the Wolverine trial occurring on December 22, 2014 – well before the start of the Class Period – while the Defendants were in possession of undisclosed trial data from the ongoing Pilot Phase 2 trial that directly impacted the Wolverine trial.

255. Following the December 2014 amendments, Defendants continued to manipulate the outcome measures of the Wolverine trial throughout August and September 2015 to remove or reduce the trial's burden of proving durational outcomes which, as Defendants knew in light of the undisclosed Pilot Phase 2 trial results, PNT2258 would never satisfy. Then, in November 2015, Pronai altered the inclusion criteria in the Wolverine trial to skew the patient population towards healthier, more treatable patients (not the patients for which the trial was intended to treat), in a

transparent effort to boost the trial's efficacy results after incoming data showed sicker subjects were not responding to treatment with PNT2258.

256. Defendants made similar amendments to the Brighton trial as it was ongoing. The most significant modification to the Brighton trial protocol was implemented on March 10, 2016, only two weeks after the Company's February 29, 2016 enrollment cut-off to conduct an interim analysis of patients in the Wolverine trial. Thus, while admittedly in possession of interim data from the Wolverine trial, Defendants altered the inclusion criteria in the Brighton trial to skew the patient population towards healthier, more treatable patients.

257. As Defendants themselves have acknowledged, before implementing the protocol modifications in the Wolverine and Brighton trials, Pronai was required to submit a protocol amendment to both the FDA and the trial's IRBs at each clinical trial site that was supported by actual clinical data from the ongoing trial. Moreover, according to CW4, Defendant Glover approved all important amendments to the trial protocol.

258. During the Class Period, the Wolverine trial had 27 trial sites and the Brighton trial had 9 trial sites. Thus, the Defendants would have known at least several months before the protocol amendments beginning in December 2014 that PNT2258 was failing to meet its efficacy endpoints, patients were not responding to treatment, and patients were discontinuing treatment en masse due to disease progression and/or death because: (i) they approved and prepared the protocol amendments; and (ii) Pronai was required to monitor patient deaths and had an obligation to report each death promptly to the FDA.

259. Yet these modifications were inexplicably never disclosed to investors in contravention of industry practices and the Company's own post-Class Period behavior, allowing the Company's common stock to remain artificially inflated throughout the Class Period. Pronai

also never disclosed to investors that it was *excluding* patients who had the poorest response (i.e., those enrolled before the November 15 amendment in the Wolverine trial) from the efficacy data ultimately announced – a plain violation of FDA policy and guidance.

C. Defendants' Own Ongoing Internal Studies and Experiments Demonstrated PNT2258 Would Never be an Effective Treatment for Relapsed or Refractory DLBCL and RCLL

260. As discussed above, prior internal Company studies and early PNT2258 clinical trials showed that PNT2258 was not producing evidence of efficacy and would never be an effective treatment for relapsed or refractory DLBCL and/or RCLL.

261. Specifically, according to CW1 and CW2, numerous internal studies conducted by these witnesses demonstrated that DNAi was ineffective and not a "real" technology and that PNT2258 demonstrated it was not an effective treatment. CW1 and CW2 attended various meetings during the Class Period where the failed study results were discussed, including meetings attended by Defendant Glover. Thus, Defendants were aware that Pronai's internal studies did not support the efficacy of PNT2258 and continuing its clinical trials.

D. The Individual Defendants Knew PNT2258 Was Failing to Meet its Efficacy Endpoints in the Wolverine and Brighton Trials Because PNT2258 was Pronai's "Lead Drug Product" and, thus, Constituted its "Core" Business

262. As alleged herein, during the Class Period, PNT2258 was Pronai's "lead drug product" and the Company's ***only*** drug in clinical development. The Company has stated that its "business and future success depends on [its] ability to successfully develop, obtain regulatory approval for and commercialize [its] only clinical product candidate, PNT2258" and further warned that "if [it is] unable to successfully develop, obtain regulatory approval for and commercialize PNT2258, or experience significant delays in doing so, [its] business will be materially harmed."

263. Given that PNT2258 was Pronai's only viable drug product and the Company's financial viability depended on the success of PNT2258, during the Class Period PNT2258 constituted the Company's "core business operations" and a "vital corporate function" that Pronai's most senior executives are rightly presumed to have knowledge of as a matter of law. Indeed, according to the Company's 2015 Annual Report, as of December 31, 2015, Pronai had only 52 employees and one clinical drug candidate – PNT2258 – and thus, knowledge of the Company's false public statements is virtually inexplicable absent fraud.

264. Moreover, as discussed above, there was a significant potential market for PNT2258 and other DNAi drugs as a result of the drastic unmet medical need for oncology drugs capable of impacting oncogenic targets like BCL2 after other traditional therapies failed, thereby further demonstrating the drug's importance to Pronai's business.

E. The Suspiciously Timed Resignations of Three Board Members, the Chief Scientific Officer, and the Chief Medical Officer Support an Inference of Scienter

265. Shortly after Defendants' November 2015 protocol amendment altering the patient inclusion criteria for the Wolverine trial, three members of the Board (including a majority of the Company's Audit Committee) and the Company's Chief Scientific Officer resigned over the course of only three months. Moreover, the day after the Company announced interim data from the Wolverine trial on April 25, 2016, Pronai's Chief Medical Officer, Richard Messmann, notified the Company of his decision to resign on April 26, 2016.

266. More specifically, on December 9, 2015, less than one month after Pronai implemented its protocol amendment to the inclusion criteria in the Wolverine trial, the Company announced that Peter Thompson, M.D., had notified Pronai of his decision to resign from the Company's Board and Audit Committee. One month after Thompson's resignation, on January

25, 2016, Pronai announced that Wendi Rodrigueza had notified Pronai of her decision to resign as the Company's Chief Scientific Officer. Then, on March 4, 2016, Pronai announced that Alvin Vitangcol had notified the Company of his decision to resign from the Board and Audit Committee. Also on March 4, 2016, Pronai announced that Albert Cha had notified the Company of his decision not to stand for re-election at the Company's 2016 annual meeting of stockholders.

267. In the midst of this mass exodus, Pronai conducted its interim analysis for all data collected in the Wolverine trial on April 25, 2016 for patients enrolled as of February 29, 2016, which showed that PNT2258 would fail to achieve its efficacy endpoints – regardless of how many times the Company manipulated trial protocol. While this data would not be revealed to Pronai investors for several more months, only *the following day*, on April 26, 2016, Pronai's Chief Medical Officer Richard Messmann notified the Company of his decision to resign.

268. As the Chief Medical Officer and Chief Scientific Officer, both Richard Messmann and Wendi Rodrigueza, respectively, were responsible for designing, implementing, and monitoring the clinical trials of PNT2258. Thus, the sudden, unexplained, and suspicious departures of a majority of the Company's Audit Committee and key executives, provides strong additional support that they and the Defendants knew of the Company's pervasive fraud during their tenure with the Company.

F. The Company's Abrupt Change in Corporate Strategy Further Supports an Inference of Scienter

269. In the midst of the protocol amendments to both the Wolverine and Brighton trials, the Company subtly and inexplicably changed its corporate strategy. As detailed above, throughout the former half of the Class Period, the Company's self-proclaimed "primary goal" and "clinical development strategy," was "to exploit the full commercial potential of PNT2258 by developing the product candidate in earlier lines of therapy in DLBCL." To this end, the Company

initially announced on August 21, 2015 that it planned to initiate three additional Phase 2 trials of PNT2258 during 2016.

270. Yet over the course of the Class Period, as Pronai continued to receive efficacy data from the failing Wolverine and Brighton trials, this strategy (like the Wolverine and Brighton trial protocols) was modified and later entirely abandoned and the Company's purported corporate strategy was replaced with a strategy focused on "building a broad and diverse pipeline of target oncology drugs" through the acquisition of new oncology therapeutics.

271. The timing of the disclosure modifications often correlated with dates on which the Defendants were in possession of negative, material non-public information regarding the ongoing Wolverine and Brighton trials. For example, the Company first mentioned the potential acquisition of a new "oncology drug asset[]" on December 3, 2015, less than one month after it implemented a protocol amendment to the Wolverine trial to skew the patient population towards patients with better lower ECOG scores who had been more successful in the Phase 1 safety trial.. Thereafter, Pronai repeatedly admitted to hiring new Company executives for the express purpose of acquiring other oncology drug candidates and entirely abandoned discussing additional Phase 2 trials for PNT2258.

272. This disclosure further evidence's Defendants' knowledge that the DNAi platform and PNT2258 "lead drug product" would never be a successful third-line therapy.

II. THE INDIVIDUAL DEFENDANTS HAD MOTIVE TO COMMIT THE ALLEGED FRAUD IN ORDER TO SELL STOCK IN THE IPO AT ARTIFICIALLY INFLATE PRICES

273. The Individual Defendants were motivated to engage in the alleged fraudulent scheme and issue materially false and misleading statements and/or omit material facts in order to inflate Pronai's stock price and maximize proceeds from the July 2015 IPO.

274. Unbeknownst to investors at the time of the IPO: (i) ongoing studies and internal Company experiments demonstrated DNAi and PNT2258 were ineffective; (ii) undisclosed data from the Pilot Phase 2 study showed patients experienced disease progression at a faster rate when treated with PNT2258 than traditional therapies; and (iii) efficacy data from the ongoing Wolverine trial showed enrolled patients were not responding to treatment with PNT2258. Thus, an IPO needed to occur, if at all, before the interim results from the Wolverine trial were publicly announced the Company's stock price plummeted as a result.

275. By artificially inflating the common stock price in anticipation of the IPO, Pronai was able to generate approximately $158.4 million in net proceeds to fund the Company's acquisition of an alternative drug candidate - AS-141 – only three business days before the Defendants announced the Wolverine and Brighton trials had woefully failed to establish the efficacy of PNT2258 to justify its continued development. The proceeds from this offering obviously would have been negatively impacted if the truth about the Company's tenuous chances of achieving FDA approval for PNT2258, and the drug's lack of efficacy, were actually disclosed.

276. The foregoing creates an inference of scienter and motive on behalf of the Defendants relating to the IPO.

LOSS CAUSATION

277. During the Class Period, Defendants materially misled the investing public about the efficacy of PNT2258 and the DNAi platform, thereby inflating the price of Pronai's common stock.

278. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiffs and other members of the Class. As described herein, during the

Class Period, the Defendants named in this Action made or caused to be made a series of materially false and/or misleading statements about PNT2258, its effectiveness, and the ongoing Wolverine and Brighton trials. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its well-being and prospects, thus causing the Company's stock to be overvalued and artificially inflated at all relevant times. The materially false and/or misleading statements made by the Defendants named in this Action during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company's stock at artificially inflated prices, thus causing the damages complained of herein. For example:

- In response to Pronai's 2015 Third Quarter Report announcing *inter alia* that PNT2258 had produced "evidence of efficacy and tolerability" that would provide the "foundation for a global registration strategy," the Company's stock price increased 11.5% from $17.46 per share on November 5, 2015 to $19.47 per share on November 9, 2015.

- In response to Defendant Glover's November 19, 2015 presentation at the Jefferies Autumn 2015 Global Healthcare Conference in London touting the Company's "[n]oval [DNAi] platform" and the positive "efficacy and durability" of PNT2258, the Company's stock price increased 3.5% from $17.52 per share on November 19, 2015 to $18.13 per share on November 23, 2015.

- In response to Pronai's 2015 Annual Report filed with the SEC on March 3, 2016, which represented that PNT2258 had produced "evidence of efficacy and tolerability" and would treat "a variety of oncology indications," the Company's stock price increased 9.36% from $6.41 per share on March 3, 2016 to $7.01 per share on March 7, 2016.

- In response to Pronai's 2016 First Quarter Reported filed with the SEC on May 10, 2016, which touted that PNT2258 had produced "evidence of efficacy and tolerability," which would form the "foundation of a global registration strategy for PNT225," the Company's stock price increased 15.5% from $4.66 per share on May 9, 2016 to $5.38 per share on May 10, 2016.

279. During the Class Period, as detailed herein, the Defendants engaged in a scheme to deceive the market and perpetuate a course of conduct that caused the price of Pronai common

stock to be artificially inflated by failing to disclose and/or misrepresenting the adverse facts detailed herein. As the Defendants' misrepresentations and fraudulent conduct were disclosed and became apparent to the market, the artificial inflation in the price of Pronai shares was removed, and the price of Pronai shares fell.

280. For example, in response to the June 6, 2016 Press Release disclosing interim data from the Wolverine Phase 2 trial and the full abandonment of the Company's DNAi platform, the Company's stock price decreased a tremendous 67% from $6.38 per share on June 3, 2016 to close at $2.07 per share on June 6, 2016.

281. As a result of their purchases of Pronai securities during the Class Period at artificially inflated prices, Plaintiffs, and the other Class members suffered economic loss, *i.e.*, damages, under the federal securities laws. The timing and magnitude of the price decline in Pronai shares negate any inference that the loss suffered by Plaintiffs and the other Class members was caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to the Defendants' fraudulent conduct.

CLASS ACTION ALLEGATIONS

282. Plaintiffs bring this action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of a class of all persons or entities that purchased or otherwise acquired Pronai securities between July 15, 2015 and June 6, 2016, inclusive, seeking to pursue remedies under the Exchange Act.

283. Excluded from the Class are Pronai and its subsidiaries and affiliates, and their respective officers and directors at all relevant times, and any of their immediate families, legal representatives, heirs, successors, or assigns, and any entity in which any Defendant has or had a controlling interest.

284. Because Pronai had millions of shares outstanding during the Class Period, and because its shares were actively traded on the NASDAQ, the members of the Class are so numerous that joinder of all Class members is impracticable. While the exact number of Class members is unknown at this time and can only be ascertained through discovery, Plaintiffs believe that there are, at a minimum, thousands of Class members. Members of the Class may be identified from records maintained by Pronai or its transfer agent and may be notified of the pendency of this action by mail, using forms of notice customarily used in securities class actions.

285. Plaintiffs' claims are typical of those of the members of the Class, as all Class members have been similarly affected by Defendants' wrongful conduct as alleged herein.

286. Plaintiffs will fairly and adequately protect the interests of the Class and have retained counsel competent and experienced in class action and securities litigation.

287. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. These common questions include:

a. Whether Defendants violated the federal securities laws as alleged herein;

b. Whether Defendants' statements to the investing public during the Class Period misrepresented material facts about Pronai's business and operations;

c. Whether the price of Pronai shares was artificially inflated during the Class Period; and

d. The extent to which members of the Class have sustained damages and the proper measure of damages.

288. A class action is superior to all other available methods for the fair and efficient adjudication of this matter as joinder of all Class members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden

of individual litigation make it impossible for Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

NO STATUTORY SAFE HARBOR

289. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Amended Class Action Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward- looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Pronai who knew that the statement was false when made.

APPLICABILITY OF FRAUD ON THE MARKET DOCTRINE

290. The market for Pronai common stock was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Pronai stock traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased or otherwise acquired the Company's stock relying upon the integrity of the market price of Pronai and market information relating to the Company, and have been damaged thereby.

291. During the Class Period, the artificial inflation of Pronai stock was caused by the material misrepresentations and/or omissions particularized in this Amended Complaint causing the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, the Defendants named in this Action made or caused to be made a series of materially false and/or misleading statements about PNT2258's efficacy. These material misstatements and/or omissions created an unrealistically positive assessment of Pronai and its business, operations, and prospects, thus causing the price of the Company's stock to be artificially inflated at all relevant times.

292. When the truth was revealed, it negatively affected the value of the Company shares. The Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company's stock at such artificially inflated prices, and each of them has been damaged as a result.

293. At all relevant times, the market for Pronai common stock was an efficient market for the following reasons:

a. Pronai common stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

b. As a regulated issuer, Pronai filed periodic public reports with the SEC and the NASDAQ;

c. Pronai communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

d. During the class period, on average, over several hundreds of thousands of shares of Pronai stock were traded on a weekly basis. On news days, the Company's trading volume increased into the millions, reflecting an active trading market for Pronai common stock and investors' expectations being impounded into the stock price; and

e. The proportion of statistically significant stock price movement days for Pronai common stock on news days is significantly over the proportion of non-news days and, thus, Pronai common stock is more likely to have a statistically significant return on a day with news than no-news, consistent with an informationally efficient market.

COUNT I

For Violations of Section 10(b) of the Exchange Act and Rule 10b-5

Against Pronai and the Individual Defendants

294. Plaintiffs reallege each allegation as if fully set forth herein.

295. This claim is brought under §10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5, against Pronai, Glover, and Jagpal (the "Count I Defendants").

296. The Count I Defendants: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material fact and/or omitted material facts necessary to make the statements made not misleading; and (c) engaged in acts, practices and a course of business which operated as a fraud and deceit upon Plaintiffs and the Class, in violation of §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

297. The Count I Defendants individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct to conceal non-public, adverse material information about the

Company's outlook and condition, as reflected in the misrepresentations and omissions set forth above.

298. The Count I Defendants each had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth by failing to ascertain and to disclose such facts even though such facts were available to them, or deliberately refrained from taking steps necessary to discover whether the material facts were false or misleading.

299. As a result of the Count I Defendants' dissemination of materially false and misleading information and their failure to disclose material facts, Plaintiffs and the Class were misled into believing that the Company's statements and other disclosures were true, accurate, and complete.

300. Pronai is liable for the acts of the Individual Defendants and other Company personnel referenced herein under the doctrine of respondeat superior, as those persons were acting as the officers, directors, and/or agents of Pronai in taking the actions alleged herein.

301. Plaintiffs and the Class purchased Pronai securities, without knowing that the Count I Defendants had misstated or omitted material facts about the Company's performance or prospects. In so doing, Plaintiffs and the Class relied directly or indirectly on false and misleading statements made by the Count I Defendants, and/or an absence of material adverse information that was known to the Count I Defendants or recklessly disregarded by them but not disclosed in the Count I Defendants' public statements. Plaintiffs and the Class were damaged as a result of their reliance on the Count I Defendants' false statements and misrepresentations and omissions of material facts.

302. At the time of the Count I Defendants' false statements, misrepresentations and omissions, Plaintiffs and the Class were unaware of their falsity and believed them to be true. Plaintiffs and the Class would not otherwise have purchased Pronai stock had they known the truth about the matters discussed above.

303. By virtue of the foregoing, the Count I Defendants have violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

304. As a direct and proximate result of the Count I Defendants' wrongful conduct, Plaintiffs and the Class have suffered damages in connection with their purchase of Pronai securities.

305. This action was filed within two years of discovery of the fraud and within five years of Plaintiffs' purchases of securities giving rise to the cause of action.

COUNT II

For Violations of Section 20(a) of the Exchange Act

Against Pronai and the Individual Defendants

306. Plaintiffs reallege each allegation as if fully set forth herein.

307. This claim is brought under §20(a) of the Exchange Act, 15 U.S.C. § 78t, against Pronai, Glover, and Jagpal (the "Count II Defendants").

308. Each of the Count II Defendants, by reason of their status as senior executive officers and/or directors of Pronai, directly or indirectly, controlled the conduct of the Company's business and its representations to Plaintiffs and the Class, within the meaning of §20(a) of the Exchange Act. The Count II Defendants directly or indirectly controlled the content of the Company's SEC statements and press releases related to Plaintiffs' and the Class' investments in Pronai securities within the meaning of §20(a) of the Exchange Act. Therefore, the Count II Defendants are jointly and severally liable for the Company's fraud, as alleged herein.

309. The Count II Defendants controlled and had the authority to control the content of the Company's SEC statements and press releases. Because of their close involvement in the everyday activities of the Company, and because of their wide-ranging supervisory authority, the Count II Defendants reviewed or had the opportunity to review these documents prior to their issuance, or could have prevented their issuance or caused them to be corrected.

310. The Count II Defendants knew or recklessly disregarded the fact that Pronai's representations were materially false and misleading and/or omitted material facts when made. In so doing, the Count II Defendants did not act in good faith.

311. By virtue of their high-level positions and their participation in and awareness of Pronai's operations and public statements, the Count II Defendants were able to and did influence and control Pronai's decision-making, including controlling the content and dissemination of the documents that Plaintiffs and the Class contend contained materially false and misleading information and on which Plaintiffs and the Class relied.

312. The Count II Defendants had the power to control or influence the statements made giving rise to the securities violations alleged herein, and as set forth more fully above.

313. As set forth herein, the Count II Defendants each violated §10(b) of the Exchange Act and Rule 10b-5, thereunder, by their acts and omissions as alleged herein. By virtue of their positions as controlling persons, the Count II Defendants are also liable pursuant to §20(a) of the Exchange Act.

314. As a direct and proximate result of the Count II Defendants' wrongful conduct, Plaintiffs and the Class suffered damages in connection with their purchase of Pronai securities.

315. This action was filed within two years of discovery of the fraud and within five years of Plaintiffs' purchases of securities giving rise to the cause of action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

A. Declaring this action to be a proper class action pursuant to Rule 23 of the Federal Rules of Civil Procedure and certifying Plaintiffs as representatives of the Class;

B. Awarding Plaintiffs and the members of the Class damages, including interest;

C. Awarding Plaintiffs reasonable costs and attorneys' fees; and

D. Awarding such other relief as the Court may deem just and proper.

JURY DEMAND

In accordance with Fed. R. Civ. P. 38(b), Plaintiffs demand a jury trial of all issues involved, now, or in the future, in this action.

Dated: March 17, 2017

/s/ *Shannon L. Hopkins*

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CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of March, 2017, true and correct copies of this document were served via this Court's ECF system to all counsel of record as identified on the Notice of Electronic Filing (NEF), and electronically sent to those indicated as non-registered participants.

/s/ Shannon L. Hopkins
Shannon L. Hopkins